



Legislation and Regulation Committee

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LEGISLATION AND REGULATION COMMITTEE

PART A: LEGISLATION REPORT

1. Board Sponsored Legislation

ATTACHMENT A-1

SB 1489 (Senate Business Professions and Economic Development Committee) – Omnibus
(Chapter 653, Statutes of 2010, effective 1/1/2011)

At the January 2010 Board Meeting, the board voted to pursue several omnibus provisions, which were introduced in SB 1489. The measure was amended on June 17, 2010, to modify §4013 (subscriber alert provisions) and was again amended on August 12, 2010, to modify §4076.5 (patient-centered labels), as summarized below.

Attachment A-1 contains pages relevant to the Board of Pharmacy. The entire bill can be viewed at <http://www.leginfo.ca.gov>.

General Omnibus Provisions

§4013. Subscriber Alert. Section 4013 was amended at the request of industry, which had concerns about the implementation of the e-mail notification requirement that went into effect July 1, 2010. Amendments allow an owner of two or more pharmacies the option of registering with the board one e-mail address, by which the owner will immediately transmit any board e-mail notification to its licensed facilities.

§4076.5. Patient-Centered Prescription Labels. Section 4076.5 was amended to give the board the authority to exempt from prescription labeling requirements (16 CCR §1707.5.) prescriptions dispensed to a patient in a health facility as defined in Section 1250 of the Health and Safety Code, so long as the prescriptions are administered by a licensed health care professional. Prescriptions dispensed upon discharge, or those not administered by a health

care professional are subject to the board's regulation. Additional amendments also authorize the board to exempt from prescription labeling regulations a prescription dispensed to a patient, so long as certain criteria is met (i.e., home infusion, specialty therapies, etc.).

§4101. Veterinary Food-Animal Drug Retailer

§4196(e). Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repackaged

Add §4200.1. Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x failure)
Recodification of exact language previously in statute (which had sunset in 2009)

Amendments to update references to the California Department of Public Health and the Physical Therapy Board of California

§4017. Authorized Officers of the Law

§4028. Definition of Licensed Hospital

§4037. Definition of Pharmacy

§4052.3. Emergency Contraception Drug Therapy; Requirements and Limitations

§4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

§4072. Oral or Electronic Transmission of Prescription – Health Care Facility

§4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

§4127.1. License to Compound Injectable Sterile Drug Products Required

§4169. Prohibited Acts (also, to strike operative date of 2008)

§4181(a). License Requirements; Policies and Procedures; Who May Dispense

§4191(a). Compliance with the California Department of Public Health; Who May Dispense Drugs

Amendments to update references to the Department of Health Care Services (formerly known as the Department of Health Services)

§4425. Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring

§4426. California Department of Health Care Services to Study Reimbursement Rates

2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Copies of each measure are provided in Attachment A-2.

ATTACHMENT A-2

a. Chaptered Legislation

Board of Pharmacy

AB 2104 (Hayashi, Chapter 374, Statutes of 2010). Requires that the Director of the DCA approve the board's appointment of the Executive Officer. The board had established an Oppose position on this measure.

Licensing / General / Other

A. AB 2699 (Bass, Chapter 270, Statutes of 2010) – Licensure exemption, State of Emergency

Existing law provides for an exemption from licensure and regulation requirements for a healing arts practitioner licensed in another state that offers or provides health care for which he or she is licensed, during a state of emergency. The provisions of AB 2699 provide other exemptions from licensure until January 2014, if the care is provided through a sponsored event and under specific circumstances. A practitioner would be exempt from state requirements for licensure, so long as the following criteria are met:

Obtains authorization from the board by providing a valid license and photo identification;

Has not committed any act or been convicted of a crime constituting grounds for denial of a license;

Has the appropriate education;

Agrees to comply with all practice requirements; and

Pays a fee determined by the board by regulation which shall cover the cost of processing the request.

A sponsoring entity seeking to provide health care services must register with the Board by completing a registration form and provide this information to the health department. Within 15 days of the health care services, the sponsoring entity would be required to file a report with the board that contains the description of care provided, and a list of practitioners providing the service. The board may revoke registration if the sponsoring entity fails to comply. Although a pharmacist falls within the definition of a health care provider and, therefore, could be included in the provisions of his bill, the author's office indicated that Pharmacists would most likely not be participating in events referenced in the measure.

B. SB 1172 (Negrete McLeod, Chapter 517, Statutes of 2010) – Diversion Programs

This bill requires specified healing arts boards (including the Board of Pharmacy) to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. The bill authorizes the board to adopt regulations to order a licensee (on probation or in a diversion program) to cease practice for (1) major violations, or (2) when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to uniform and specific standards, as specified.

Participants in the board's Pharmacists Recovery Program (PRP) who test positive for any prohibited substance currently are removed from work pending the receipt of two negative tests. The board did not take a position on this bill.

C. AB 1414 (Hill, Chapter 76, Statutes of 2010) – Controlled Substances: Apomorphine (From Schedule II to Schedule V)

The California Uniform Controlled Substances Act currently lists Apomorphine as a Schedule II controlled substance. This bill moves Apomorphine from Schedule II to Schedule V. Schedule V drugs are generally defined by those drugs that have a currently accepted medical value, present a low potential for abuse, and may lead to limited psychological or physical dependence. Schedule V substances include cough suppressants and pain modulators, as well as many prescription drugs. There was no noted opposition to the measure, and the board did not take a position on this bill.

Sunset Review and Legislative Oversight Proposals

A. AB 1659 (Huber, Chapter 666, Statutes of 2010) – State Government, Agency Repeals

B. AB 2130 (Huber, Chapter 670, Statutes of 2010) – Joint Committee on Boards, Commissions and Consumer Protection

AB 1659 creates a new Joint Sunset Review Committee with the responsibility to review and evaluate specified state agencies (including the Board of Pharmacy) based on specific criteria and information provided by these agencies. AB 2130 is a companion bill that abolishes the (current) Joint Committee on Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Joint Sunset Review Committee.

The board currently has a sunset date of January 1, 2013. Under the current sunset review process, if the board's sunset date is not extended beyond 2013, the Board of Pharmacy's duties and responsibilities would fall to the Department of Consumer Affairs, and the board – in effect – would operate as a bureau within DCA. The provisions that created this process were repealed in this measure. Therefore, effective January 1, 2011, should any board currently under the Department of Consumer Affairs sunset, that profession will no longer be regulated as there is no provision to transfer the board's duties and responsibilities to DCA. In effect, if the board's sunset date is not extended, the board would cease to exist and the practice of pharmacy would be unregulated.

The department is aware of this issue and is exploring options to remedy this.

Distribution of Needles and Syringes

AB 1701 (Chesbro, Chapter 667, Statutes of 2010)

In 2004, the Disease Prevention Demonstration Project pilot was launched, with a sunset date of 2010, to allow a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time, as specified. AB 1701 extends these provisions to 2018. The board did not take a position on this bill.

Other Legislation Impacting the Board or the Board's Jurisdiction

A. SB 294 (Negrete McLeod, Chapter 695, Statutes of 2010) – Professions and Vocations: Regulation

This bill resets the sunset dates of various boards within the Department of Consumer Affairs, but does not impact the Board of Pharmacy. The board did not take a position on this bill.

B. SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) – Healing Arts: Peer Review

Existing law provides for a peer review process of licentiate and that certain information regarding judgments and settlements is reported. This bill requires that in addition to current requirements, any additional exculpatory or explanatory statements submitted by the licentiate also be included; the bill also requires the agency to inform the licentiate that information submitted electronically will be publicly disclosed to those who request the information. The board did not take a position on this bill.

b. Vetoed Legislation

Copies of each measure and the related Veto Message are provided in Attachment 3.

ATTACHMENT A-3

A. AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services

Board position: None. This bill would have allowed the California Department of Public Health to authorize entities to provide hypodermic needles and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease through the sharing of unclean hypodermic needles and syringes; and provided that a participant in a clean needle and syringe exchange program shall not be subject to criminal prosecution for possession of needles and syringes acquired under an approved program.

B. AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Board position: *Support*. This bill would have provided for centralized pharmacy packaging in a hospital, where the pharmacy could be located outside of a hospital on either the same premises or separate premises regulated under a hospital's license.

C. AB 2747 (Lowenthal) – Prisoners; Pharmacy Services

Board position: None. This bill would have authorized the California Department of Corrections and Rehabilitation (CDCR) to operate and maintain a centralized pharmacy distribution center for facilities under its jurisdiction.

D. SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

Board position: None. This bill would have established requirements for providers of blood clotting products for home use whose products are used to treat hemophilia and other bleeding disorders, and designated the Board of Pharmacy to administer and enforce the provisions of the Standards of Service for Providers of Blood Clotting Products and Home Use Act.

E. SB 1029 (Yee) – Hypodermic Needles and Syringes

Board position: None. This bill would have allowed a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 30 years of age or older. The bill addressed the storage of products to ensure they would be available only to authorized personnel, would have required that disposal options are provided to consumers, and would have required pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

3. Legislation That Failed Passage

- A. SB 1390 (Corbett) – Patient-Centered Prescription Labels
- B. AB 1455 (Hill) – Ephedrine; Retail Sale
- C. SB 1071 (DeSaulnier) – CURES
- D. SB 1106 (Yee) – Prescribers Dispensing of Samples
- E. AB 2551 (Hernandez) – Pharmacy Technician: Scholarship & Loan Repayment Program
- F. AB 1310 (Hernandez) – Healing Arts Database

3. FOR DISCUSSION AND POSSIBLE ACTION: Legislation for Sponsorship During 2011-2012 Session

1. Previously-Approved Board-Sponsored Legislation for 2011/2012

ATTACHMENT A-4

A. Section 4362 – Entry Into the Pharmacists Recovery Program (Omnibus proposal)

In January 2010, the board voted to pursue an omnibus proposal to add Section 4362, to establish a co-pay for participants in the Pharmacists Recovery Program to offset a portion of the board’s administrative fee for each participant. The proposal was not picked up for the 2009/2010 Legislative Session.

B. Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors

Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. The board voted in January 2010 to pursue sponsorship of such legislation, to include the provisions below. These were not picked up in the 2009/2010 session.

a. Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines “dispensed” for purposes of this section only. This provision was approved in concept only by the board in January 2009.

- b. Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines “licensed integrated waste hauler” for purposes of this section only. This provision was approved in concept only by the board in January 2009.

- c. Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. (Language for the later provision will require development.) This provision has not previously been considered by the committee or the board.

C. Sections 4104, 4105 and 4112 – Enforcement Enhancements

The board voted at its meeting in January 2010 Board Meeting to pursue statutory changes as outlined in Sections 4104 and 4112. Proposed amendments to § 4105 mirror those contained in proposed changes to § 4081, related to the production of records, when requested by the board.

- a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee’s theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

- b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

- c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

2. Legislation for Consideration During 2011/2012 Legislative Session

ATTACHMENT A-5

The provisions below are offered for consideration for the 2011/2012 legislative session.

A. Section 4200 – Pharmacist Examination (Omnibus Provision)

This amendment would remove an obsolete reference in the pharmacist license requirements. A copy of the proposed language is provided in Attachment 5.

B. Section 4301.1 – To Allow the Board to Suspend the License of a Pharmacist or Pharmacist Intern for a Felony Conviction for a Crime of Unprofessional Conduct.

In October 2009, the Legislation and Regulation Committee considered a staff proposal to add Section 4301.1. to the Business and Professions Code to provide the board with the authority to suspend the license of a pharmacist or a pharmacist intern who is convicted of a felony for a crime of unprofessional conduct, as defined in §4301; that the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so; and that the issue of penalty shall be heard by an administrative law judge, or a committee of the board with an ALJ, or the board sitting with an ALJ, at the discretion of the board. The section would allow a pharmacist or pharmacist intern to request a hearing within a specified timeframe; and that if an accusation for permanent discipline is not filed within 90 days of the suspension that the suspension shall terminate.

PART B: REGULATION REPORT

1. FOR DISCUSSION AND POSSIBLE ACTION: To Initiate a Rulemaking to Adopt 1707.6. – Notices to Consumers and Amend Section 1707.2. Notice to Consumers and Duty to Consult

ATTACHMENT B-1

Background

On June 10, 2010, the board adopted proposed regulation 16 CCR § 1707.5. to establish requirements for a patient-centered prescription drug container label. That regulation is currently undergoing administrative review.

The patient-centered prescription label regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested; it also requires a pharmacy to provide oral interpretive services.

During the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of 12-point font, as specified in the adopted regulation.

At the July 2010 Board Meeting, staff provided the board with draft language for consideration and possible action. The board discussed the draft text and directed staff to develop new draft language. At that time, the board voted to move the existing consumer notices from 16 CCR § 1702. to a new section that also includes any notice(s) regarding language interpretive services and larger font sizes.

Attachment B-1 contains newly drafted language for the committee's continued consideration and possible action.

2. FOR DISCUSSION AND POSSIBLE ACTION: Proposal to Initiate Rulemaking to Update 16 CCR § 1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge and 16 CCR § 1784 – Self Assessment by a Wholesaler by the Designated Representative in-Charge

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms provide references to relevant laws and regulations, and also serve as an easy reference guide for the Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC).

Section 1715 of Title 16 Cal. Code of Regs applies to the self-assessment of a pharmacy by the Pharmacist-in-Charge. The regulation was established in 1997 and was last amended in 2009. The following self-assessment forms are incorporated by reference in § 1715:

- 17M-13 (Rev 10/08) "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment"
- 17M-14 (Rev 10/08) "Hospital Pharmacy and Self-Assessment"

Section 1784 of Title 16 Cal. Code of Regs applies to wholesalers. This regulation was established in 2007 and was also updated in 2009. It incorporates by reference the following self-assessment form:

- 17M-26 (Rev 10/08) “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment”

After the conclusion of the 2009/2010 Legislative Session, board staff will draft changes to the self-assessment forms to reflect statutory changes for the board’s consideration at a future meeting. Copies of the self-assessment forms with proposed amendments may be provided at the meeting. Any substantive changes would be required to go through the regular rulemaking process.

3. FOR INFORMATION: Board Adopted Regulations – Approved by the Office of Administrative Law

Title 16 CCR Amend Sections 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination; Confidentiality

ATTACHMENT B-3

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

The formal rulemaking was noticed on October 30, 2009, and the 45-day comment period concluded on December 14, 2009. The board did not receive any comments to the proposed rulemaking.

The board adopted the regulation at its January 2010 Board Meeting, and the rulemaking was submitted to the department for review in March 2010. Following department approval, the rulemaking was submitted to the Office of Administrative Law for review in July 2010; that office approved the file and filed the regulation with the Secretary of State. The regulation was effective on September 17, 2010. A copy of the approved text is provided in Attachment B-3.

4. FOR INFORMATION: Board Adopted Regulations – Undergoing Administrative Review

Adoption of New Section at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Drug Container Labels

ATTACHMENT B-4

The formal rulemaking was noticed for the 45-Day Comment Period on November 20, 2009 and a regulation hearing was held on January 20, 2010. The first 15-day comment period started on February 22, 2010 and the second 15-day comment period began on April 28, 2010. The board received about 1,200 comments.

The board adopted the regulation text at its June 2010 Board Meeting. The rulemaking file was compiled and submitted to the Department for review in July 2010. The rulemaking file was transmitted to the Office of Administrative Law for review on October 5, 2010. The board is utilizing “Subscriber Alert” notifications to advise subscribers of the status of the regulation.

“Subscriber Alerts” were issued on August 11, August 31 and October 6, 2010. The Adopted Text is provided in Attachment B-4. The Final Statement of Reasons and Adopted Text have been added to the board’s Web site.

**5. FOR INFORMATION: Board Approved Regulations – Recently Noticed
(Not For Discussion At This Meeting)**

Proposed Amendments to § 1732.2. – Board Accredited Continuing Education

ATTACHMENT B-5

At the February 2010 Board Meeting, the board voted to initiate the rulemaking process to amend 16 CCR § 1732.2. related to board-accredited continuing education. The proposed text was formally noticed for comment on October 8, 2010, and the 45-day comment period concludes on November 22, 2010. A copy of the proposed regulation is provided in Attachment 4.

The proposed regulation would modify the term “continuing education *credit*” to “continuing education *hours*” and would add board-approved continued education for the following:

- A pharmacist serving on a designated subcommittee for conducting a review of exam test questions (up to 6 hours of CE)
- Attending a full-day board meeting (up to 6 hours annually)
- Attending a full committee meeting (up to 2 hours for each meeting, maximum of four hours annually)
- A pharmacist who completes the PSAM administered by the National Association of Boards of Pharmacy (up 6 hours of CE)
- Successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy (3 hours of CE)

6. Board Approved Regulations – Awaiting Notice

Proposed Amendments to § 1728. and § 1793.5., and Proposed Addition of § 1727.2., and Application Forms to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB/HIPDB)

The Licensing Committee considered at its October 5, 2010, meeting a proposal to amend Sections 1728. and 1793.5., and a proposal to add Section 1727.2. to Title 16 of the California Code of Regulations. The Licensing Committee has provided a recommendation to the board to initiate the rulemaking process to require that applicants, as specified in the proposal, submit to the board a Self Query Report from the National Practitioner Data Bank / Healthcare Integrity and Protection Data Bank (NPDB/HIPDB). For additional information, as well as a copy of the language considered, please reference the Licensing Committee materials and attachments for Items 9.b and 9.c.

7. Regulations Under Development

a. Proposed Amendments to § 1746 – Emergency Contraception Protocol

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004. The board discussed updates to the regulation at its January and July 2010 Board Meetings. Updates to the Dedicated Emergency Contraception regulation will be addressed by a subcommittee or ad hoc committee to address changes to existing drugs or the inclusion of additional drugs approved since the regulation was established six years ago. Any updates to the protocol are required to first be approved by the Medical Board prior to the board's initiation of a rulemaking.

b. Proposed Amendments to § 1751.9. – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. The proposed regulation would specify the criteria the board will utilize to consider approval of accreditation agency requests. Staff is working with counsel to develop language for consideration at a future meeting.

c. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers)

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

d. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

In 2007 the Enforcement Committee and the Board approved draft amendments to the regulation and related self-assessment form; subsequently, however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

8. Notification of Temporary Delay in Implementing New Section at Title 16 California Code of Regulations Section 1702 – Fingerprint Submissions for Pharmacists

C. First Quarterly Report on Legislation / Regulations Committees Goals for 2010/2011

ATTACHMENT C

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2007-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

Committee Discussion / Action

The committee was provided with a copy of the strategic plan in July 2010 and was asked to provide any recommended changes to the committee chair. Staff has updated the plan to reflect changes in the 1st quarter of fiscal year 10/11.

D. Request for Legislative and Regulation Changes Submitted by the Public or Staff

The committee will consider future legislative and regulatory proposals. Stakeholders are encouraged to submit these proposals in writing to the committee before or during the meeting.

E. Public Comment for Items Not on the Agenda*

The committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. *Ref: Government Code Sections 11125 and 11125.7(a)*

Adjournment

Attachment A-1

SB 1489

***Pages Relevant to Pharmacy
(Chapter 653, Statutes of 2010)***

<http://www.leginfo.ca.gov>

Senate Bill No. 1489

CHAPTER 653

An act to amend Sections 2065, 2096, 2102, 2103, 2177, 2184, 2516, 2530.2, 2539.1, 2539.6, 2570.19, 3025.1, 3046, 3057.5, 3147, 3147.6, 3147.7, 3365.5, 4013, 4017, 4028, 4037, 4052.3, 4059, 4072, 4076.5, 4101, 4119, 4127.1, 4169, 4181, 4191, 4196, 4425, 4426, 4980.40.5, 4980.43, 4980.80, 4982.25, 4984.8, 4989.54, 4990.02, 4990.12, 4990.18, 4990.22, 4990.30, 4990.38, 4992.36, 4996.17, 4996.23, 4999.46, 4999.54, 4999.58, and 4999.90 of, to add Section 4200.1 to, to add and repeal Sections 4999.57 and 4999.59 of, to repeal Sections 2026, 4980.07, 4982.2, and 4984.6 of, and to repeal Article 3 (commencing with Section 4994) of Chapter 14 of Division 2 of, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 30, 2010. Filed with
Secretary of State September 30, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1489, Committee on Business, Professions and Economic Development. Healing arts.

(1) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law requires an applicant for a physician's and surgeon's certificate whose professional instruction was acquired in a country other than the United States or Canada to provide evidence satisfactory to the board of, among other things, satisfactory completion of at least one year of specified postgraduate training.

This bill would require the applicant to instead complete at least 2 years of that postgraduate training.

Existing law requires an applicant for a physician's and surgeon's certificate to obtain a passing score on the written examination designated by the board and makes passing scores on a written examination valid for 10 years from the month of the examination for purposes of qualification for a license. Existing law authorizes the board to extend this period of validity for good cause or for time spent in a postgraduate training program.

This bill would apply this 10-year period of validity to passing scores obtained on each step of the United States Medical Licensing Examination and would also authorize the board to extend that period for an applicant who is a physician and surgeon in another state or a Canadian province and who is currently and actively practicing medicine in that state or province.

Existing law requires a licensed midwife who assists in childbirths that occur in out-of-hospital settings to annually report specified information to the Office of Statewide Health Planning and Development in March and requires the office to report to the Medical Board of California licensee

compliance with that requirement every April and the aggregate information collected every July.

This bill would require those annual reports to be made by March 30, April 30, and July 30, respectively, and would make additional changes to the information required to be reported by a midwife with regard to cases in California.

(2) Existing law provides for the licensure and regulation of speech-language pathologists, audiologists, and hearing aid dispensers by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. Existing law requires a licensed audiologist who wishes to sell hearing aids to meet specified licensure and examination requirements, and to apply for a dispensing audiologist certificate, pay applicable fees, and pass a board-approved hearing aid examination, except as specified. Existing law authorizes a licensed audiologist with an expired hearing aid dispenser's license to continue to sell hearing aids pursuant to his or her audiology license.

This bill would require the board to issue a dispensing audiology license to a licensed audiologist who meets those requirements or whose license to sell hearing aids has expired. The bill would also waive the licensure, examination, and application requirements described above as applied to a licensed hearing aid dispenser who meets the qualifications for licensure as an audiologist.

Existing law requires hearing aid dispensers and audiologists to inform a customer, in writing, that he or she should consult with a physician based upon an observation, or being informed by the customer, that certain problems of the ear exist.

This bill would additionally require that written notification upon observing or being informed by the customer of pain or discomfort in the ear or of specified accumulation or a foreign body in the ear canal.

(3) Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. Existing law authorizes the renewal of an expired license within 3 years after its expiration if the licensee files an application for renewal and pays all accrued and unpaid renewal fees and the delinquency fee prescribed by the board.

This bill would also require the licensee to submit proof of completion of the required hours of continuing education for the last 2 years.

Existing law authorizes the restoration of a license that is not renewed within 3 years after its expiration if the holder of the expired license, among other requirements, passes the clinical portion of the regular examination of applicants, or other clinical examination approved by the board, and pays a restoration fee equal to the renewal fee in effect on the last regular renewal date for licenses.

This bill would instead require the holder of the expired license to take the National Board of Examiners in Optometry's Clinical Skills examination or other clinical examination approved by the board, and to also pay any delinquency fees prescribed by the board.

Existing law alternatively authorizes the restoration of a license that is not renewed within 3 years after its expiration if the person provides proof that he or she holds an active license from another state, files an application for renewal, and pays the accrued and unpaid renewal fees and any delinquency fee prescribed by the board.

This bill would also require the person to submit proof of completion of the required hours of continuing education for the last 2 years and take and satisfactorily pass the board's jurisprudence examination. The bill would also require that the person not have committed specified crimes or acts constituting grounds for licensure denial.

(4) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and requires an applicant for a license to pass a national licensure examination and the board's jurisprudence examination. Existing law prohibits boards in the Department of Consumer Affairs from restricting an applicant who failed a licensure examination from taking the examination again, except as specified.

This bill would authorize an applicant for a pharmacist license to take the licensure examination and the jurisprudence examination 4 times each. The bill would also authorize the applicant to take those examinations 4 additional times each if additional pharmacy coursework is completed, as specified.

Existing law requires a facility licensed by the board to join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

This bill would allow an owner of 2 or more facilities to comply with the e-mail notification requirement through the use of one e-mail address under specified circumstances.

Existing law requires the California State Board of Pharmacy to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

This bill would exempt from those standardized, prescription drug label requirements prescriptions dispensed to a patient in a health facility and administered by a licensed health care professional, as specified.

(5) Existing law provides for the licensure and regulation of marriage and family therapists, licensed clinical social workers, educational psychologists, and professional clinical counselors by the Board of Behavioral Sciences. Existing law authorizes a licensed marriage and family therapist, licensed clinical social worker, or licensed educational psychologist whose license has been revoked, suspended, or placed on probation to petition the board for reinstatement or modification of the penalty, as specified. Existing law also authorizes the board to deny an application or suspend or revoke those licenses due to the revocation, suspension, or restriction by the board of a license to practice as a clinical social worker, marriage and family therapist, or educational psychologist.

This bill would make those provisions apply with respect to licensed professional clinical counseling, as specified.

Existing law requires an applicant applying for a marriage and family therapist license to complete a minimum of 3,000 hours of experience during a period of at least 104 weeks. Existing law requires that this experience consist of at least 500 hours of experience in diagnosing and treating couples, families, and children, and requires that an applicant be credited with 2 hours of experience for each hour of therapy provided for the first 150 hours of treating couples and families in conjoint therapy.

This bill would instead require that an applicant receive that 2-hour credit for up to 150 hours of treating couples and families in conjoint therapy, and would only allow an applicant to comply with the experience requirements with hours of experience gained on and after January 1, 2010.

Existing law requires an applicant for a professional clinical counselor license to complete a minimum of 3,000 hours of clinical mental health experience under the supervision of an approved supervisor and prohibits a supervisor from supervising more than 2 interns.

This bill would prohibit the board from crediting an applicant for experience obtained under the supervision of a spouse or relative by blood or marriage, or a person with whom the applicant has had or currently has a personal, professional, or business relationship that undermines the authority or effectiveness of the supervision. The bill would also delete the provision prohibiting a supervisor from supervising more than 2 interns.

Existing law requires an associate clinical worker or an intern to receive an average of at least one hour of direct supervisor contact for every 10 hours of client contact in each setting and authorizes an associate clinical worker or an intern working in a governmental entity, a school, college, or university, or a nonprofit and charitable institution to obtain up to 30 hours of the required weekly direct supervisor contact via two-way, real time videoconferencing.

This bill would delete that 30-hour limit and would require an associate clinical worker or an intern to receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of face-to-face psychotherapy, as defined, is performed in each setting in which experience is obtained.

Existing law imposes specified requirements with respect to persons who apply for a professional clinical counselor license between January 1, 2011, and June 30, 2011, inclusive. Existing law imposes specified unit requirements on applicants who hold degrees issued prior to 1996.

This bill would include within those requirements specified units of supervised practicum or field study experience.

Existing law imposes specified requirements with respect to persons who apply for a professional clinical counselor license between January 1, 2011, and December 31, 2013, inclusive. With respect to those applicants, existing law authorizes the board to accept experience gained outside of California if it is substantially equivalent to that required by the Licensed Professional Clinical Counselor Act and if the applicant has gained a minimum of 250

hours of supervised clinical experience in direct counseling in California while registered as an intern with the board.

This bill would eliminate that 250-hour requirement with respect to persons with a counseling license in another jurisdiction, as specified, who have held that license for at least 2 years immediately prior to applying with the board.

Existing law authorizes the board to refuse to issue or suspend or revoke a professional clinical counselor license or intern registration if the licensee or registrant has been guilty of unprofessional conduct, as specified.

This bill would specify that unprofessional conduct includes (1) engaging in conduct that subverts a licensing examination, (2) revocation, suspension, or restriction by the board of a license to practice as a clinical social worker, educational psychologist, or marriage and family therapist, (3) conduct in the supervision of an associate clinical social worker that violates the profession's governing professional clinical counseling or regulations of the board, and (4) failing to comply with required procedures when delivering health care via telemedicine.

The bill would make other technical, nonsubstantive changes in various provisions governing the healing arts and would delete certain obsolete and duplicative language.

(6) This bill would incorporate additional changes in Section 2177 of the Business and Professions Code proposed by SB 1410, to be operative if SB 1410 and this bill become effective on or before January 1, 2011, and this bill is enacted last.

(7) This bill would incorporate additional changes in Section 2570.19 of the Business and Professions Code proposed by SB 294 and SB 999, to be operative if SB 294 and SB 999, or either of them, and this bill become effective on or before January 1, 2011, and this bill is enacted last.

(8) This bill would incorporate additional changes in Section 4980.43 of the Business and Professions Code proposed by AB 2435, to be operative if AB 2435 and this bill become effective on or before January 1, 2011, and this bill is enacted last.

(9) This bill would incorporate additional changes in Section 4996.17 of the Business and Professions Code proposed by AB 2167, to be operative if AB 2167 and this bill become effective on or before January 1, 2011, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. Section 2026 of the Business and Professions Code is repealed.

SEC. 2. Section 2065 of the Business and Professions Code is amended to read:

2065. Unless otherwise provided by law, no postgraduate trainee, intern, resident, postdoctoral fellow, or instructor may engage in the practice of medicine, or receive compensation therefor, or offer to engage in the practice

SEC. 18. Section 3365.5 of the Business and Professions Code is amended to read:

3365.5. (a) Whenever any of the following conditions are found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, a licensee shall, prior to fitting or selling a hearing aid to any individual, suggest to that individual in writing that his or her best interests would be served if he or she would consult a licensed physician specializing in diseases of the ear or if no such licensed physician is available in the community then to a duly licensed physician:

- (1) Visible congenital or traumatic deformity of the ear.
- (2) History of, or active drainage from the ear within the previous 90 days.
- (3) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (4) Acute or chronic dizziness.
- (5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (6) Significant air-bone gap (when generally acceptable standards have been established).
- (7) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (8) Pain or discomfort in the ear.

(b) No referral for medical opinion need be made by any licensee in the instance of replacement only of a hearing aid that has been lost or damaged beyond repair within one year of the date of purchase. A copy of the written recommendation shall be retained by the licensee for the period provided for in Section 3366. A person receiving the written recommendation who elects to purchase a hearing aid shall sign a receipt for the same, and the receipt shall be kept with the other papers retained by the licensee for the period provided for in Section 3366. Nothing in this section required to be performed by a licensee shall mean that the licensee is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of this code.

SEC. 19. Section 4013 of the Business and Professions Code is amended to read:

4013. (a) Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail notification list within 30 days of a change in the facility's e-mail address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single e-mail address to the board's e-mail notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an e-mail notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses

to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single e-mail address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its e-mail address with the board's e-mail notification list within 30 days of any change in the owner's e-mail address.

(d) This section shall become operative on July 1, 2010.

SEC. 20. Section 4017 of the Business and Professions Code is amended to read:

4017. "Authorized officers of the law" means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State Department of Public Health, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

SEC. 21. Section 4028 of the Business and Professions Code is amended to read:

4028. "Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and includes any institution classified under regulations issued by the State Department of Public Health as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

SEC. 22. Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Public Health where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

SEC. 23. Section 4052.3 of the Business and Professions Code is amended to read:

4052.3. (a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health

care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 24. Section 4059 of the Business and Professions Code is amended to read:

4059. (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Public Health. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are

certified by the Physical Therapy Board of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

SEC. 25. Section 4072 of the Business and Professions Code is amended to read:

4072. (a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the State Department of Public Health in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

- (1) Medical literacy research that points to increased understandability of labels.
- (2) Improved directions for use.
- (3) Improved font types and sizes.
- (4) Placement of information that is patient-centered.
- (5) The needs of patients with limited English proficiency.
- (6) The needs of senior citizens.
- (7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.

(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.

(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

SEC. 26. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application by the wholesaler or veterinary food-animal drug retailer and approval by the board. Any designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

SEC. 27. Section 4119 of the Business and Professions Code is amended to read:

4119. (a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

SEC. 28. Section 4127.1 of the Business and Professions Code is amended to read:

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the

board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

SEC. 29. Section 4169 of the Business and Professions Code is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received

by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

SEC. 30. Section 4181 of the Business and Professions Code is amended to read:

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 31. Section 4191 of the Business and Professions Code is amended to read:

4191. (a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 32. Section 4196 of the Business and Professions Code is amended to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A

temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

SEC. 33. Section 4200.1 is added to the Business and Professions Code, to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at a minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

SEC. 34. Section 4425 of the Business and Professions Code is amended to read:

4425. (a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

SEC. 35. Section 4426 of the Business and Professions Code is amended to read:

4426. The State Department of Health Care Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

SEC. 36. Section 4980.07 of the Business and Professions Code is repealed.

SEC. 37. Section 4980.40.5 of the Business and Professions Code is amended to read:

4980.40.5. (a) A doctoral or master's degree in marriage, family, and child counseling, marital and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling, or marriage and family therapy, obtained from a school, college, or university approved by the Bureau for Private Postsecondary and Vocational Education as of June 30, 2007, shall be considered by the board to meet the requirements necessary for licensure as a marriage and family therapist and for registration as a marriage and family therapist intern provided that the degree is conferred on or before July 1, 2010.

(b) As an alternative to meeting the qualifications specified in subdivision (a) of Section 4980.40, the board shall accept as equivalent degrees those doctoral or master's degrees that otherwise meet the requirements of this chapter and are conferred by educational institutions accredited by any of the following associations:

- (1) Northwest Commission on Colleges and Universities.
- (2) Middle States Association of Colleges and Secondary Schools.
- (3) New England Association of Schools and Colleges.
- (4) North Central Association of Colleges and Secondary Schools.
- (5) Southern Association of Colleges and Schools.

SEC. 38. Section 4980.43 of the Business and Professions Code is amended to read:

4980.43. (a) Prior to applying for licensure examinations, each applicant shall complete experience that shall comply with the following:

- (1) A minimum of 3,000 hours completed during a period of at least 104 weeks.
- (2) Not more than 40 hours in any seven consecutive days.
- (3) Not less than 1,700 hours of supervised experience completed subsequent to the granting of the qualifying master's or doctoral degree.
- (4) Not more than 1,300 hours of supervised experience obtained prior to completing a master's or doctoral degree.

Attachment A-2

Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

AB 2104 (Hayashi, Chapter 374, Statutes of 2010)

AB 2699 (Bass, Chapter 270, Statutes of 2010)

SB 1172 (Negrete McLeod, Chapter 517, Statutes of 2010)

AB 1414 (Hill, Chapter 76, Statutes of 2010)

AB 1659 (Huber, Chapter 666, Statutes of 2010)

AB 2130 (Huber, Chapter 670, Statutes of 2010)

AB 1701 (Chesbro, Chapter 667, Statutes of 2010)

SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010)

Assembly Bill No. 2104

CHAPTER 374

An act to amend Section 4003 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 25, 2010. Filed with
Secretary of State September 27, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2104, Hayashi. California State Board of Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy within the Department of Consumer Affairs. The department is under the control of the Director of Consumer Affairs. Existing law authorizes the board to appoint a person exempt from civil service designated as the executive officer who performs the duties delegated by the board.

This bill would instead authorize the board to appoint the executive officer with the approval of the director.

The people of the State of California do enact as follows:

SECTION 1. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless

a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

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Assembly Bill No. 2699

CHAPTER 270

An act to amend Section 900 of, and to add and repeal Section 901 of, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 23, 2010. Filed with Secretary of State September 24, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2699, Bass. Healing arts: licensure exemption.

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified.

This bill would also provide, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. The bill would also require an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other specified requirements, including payment of a fee as determined by the applicable licensing board. The bill would require the applicable licensing board to notify the sponsoring entity, as defined, of the sponsored event whether the board approves or denies a request for authorization to provide these services within 20 days of receipt of the request. The bill would also prohibit a contract of liability insurance issued, amended, or renewed on or after January 1, 2011, from excluding coverage of these practitioners or a sponsoring entity for providing care under these provisions.

Because this bill would expand the definition of certain crimes, the bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 900 of the Business and Professions Code is amended to read:

900. (a) Nothing in this division applies to a health care practitioner licensed in another state or territory of the United States who offers or provides health care for which he or she is licensed, if the health care is provided only during a state of emergency as defined in subdivision (b) of Section 8558 of the Government Code, which emergency overwhelms the response capabilities of California health care practitioners and only upon the request of the Director of the Emergency Medical Services Authority.

(b) The director shall be the medical control and shall designate the licensure and specialty health care practitioners required for the specific emergency and shall designate the areas to which they may be deployed.

(c) Health care practitioners shall provide, upon request, a valid copy of a professional license and a photograph identification issued by the state in which the practitioner holds licensure before being deployed by the director.

(d) Health care practitioners deployed pursuant to this chapter shall provide the appropriate California licensing authority with verification of licensure upon request.

(e) Health care practitioners providing health care pursuant to this chapter shall have immunity from liability for services rendered as specified in Section 8659 of the Government Code.

(f) For the purposes of this section, “health care practitioner” means any person who engages in acts which are the subject of licensure or regulation under this division or under any initiative act referred to in this division.

(g) For purposes of this section, “director” means the Director of the Emergency Medical Services Authority who shall have the powers specified in Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 2. Section 901 is added to the Business and Professions Code, to read:

901. (a) For purposes of this section, the following provisions apply:

(1) “Board” means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) “Health care practitioner” means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) “Sponsored event” means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) “Sponsoring entity” means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) “Uninsured or underinsured person” means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

(A) To uninsured or underinsured persons.

(B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.

(C) In association with a sponsoring entity that complies with subdivision (c).

(D) Without charge to the recipient or to a third party on behalf of the recipient.

(c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with the requirements of this section or for any act that would be grounds for denial of an application for licensure.

(d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:

(1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:

(A) The name of the sponsoring entity.

(B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.

(C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).

(D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).

(E) Any additional information required by the board.

(2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.

(e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.

(f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.

(g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.

(h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care

practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.

(i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.

(j) (1) The board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.

(2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(l) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Senate Bill No. 1172

CHAPTER 517

An act to amend Section 156.1 of, and to add Sections 315.2 and 315.4 to, the Business and Professions Code, relating to regulatory boards.

[Approved by Governor September 29, 2010. Filed with Secretary of State September 29, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1172, Negrete McLeod. Regulatory boards: diversion programs.

(1) Existing law provides for the regulation of specified professions and vocations by various boards, as defined, within the Department of Consumer Affairs. Under existing law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs are required to retain all records and documents pertaining to those services for 3 years or until they are audited, whichever occurs first. Under existing law, those records and documents are required to be kept confidential and are not subject to discovery or subpoena.

This bill would specify that those records and documents shall be kept for 3 years and kept confidential and are not subject to discovery or subpoena unless otherwise expressly provided by law.

(2) Existing law provides for the licensure and regulation of various healing arts by boards within the Department of Consumer Affairs. Under existing law, these boards are authorized to issue, deny, suspend, and revoke licenses based on various grounds and to take disciplinary action against their licensees.

Existing law establishes diversion and recovery programs to identify and rehabilitate dentists, osteopathic physicians and surgeons, physical therapists, physical therapy assistants, registered nurses, physician assistants, pharmacists and intern pharmacists, veterinarians, and registered veterinary technicians whose competency may be impaired due to, among other things, alcohol and drug abuse.

The bill would require a healing arts board to order a licensee to cease practice if the licensee tests positive for any prohibited substance under the terms of the licensee's probation or diversion program. The bill would also authorize a board to adopt regulations authorizing it to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation, as specified. The bill would provide that these provisions do not affect the Board of Registered Nursing.

The people of the State of California do enact as follows:

SECTION 1. Section 156.1 of the Business and Professions Code is amended to read:

156.1. (a) Notwithstanding any other provision of law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs shall retain all records and documents pertaining to those services until such time as these records and documents have been reviewed for audit by the department. These records and documents shall be retained for three years from the date of the last treatment or service rendered to that licentiate, after which time the records and documents may be purged and destroyed by the contract vendor. This provision shall supersede any other provision of law relating to the purging or destruction of records pertaining to those treatment and rehabilitation programs.

(b) Unless otherwise expressly provided by statute or regulation, all records and documents pertaining to services for the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs provided by any contract vendor to the department or to any board within the department shall be kept confidential and are not subject to discovery or subpoena.

(c) With respect to all other contracts for services with the department or any board within the department other than those set forth in subdivision (a), the director or chief deputy director may request an examination and audit by the department's internal auditor of all performance under the contract. For this purpose, all documents and records of the contract vendor in connection with such performance shall be retained by such vendor for a period of three years after final payment under the contract. Nothing in this section shall affect the authority of the State Auditor to conduct any examination or audit under the terms of Section 8546.7 of the Government Code.

SEC. 2. Section 315.2 is added to the Business and Professions Code, to read:

315.2. (a) A board, as described in Section 315, shall order a licensee of the board to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

SEC. 3. Section 315.4 is added to the Business and Professions Code, to read:

315.4. (a) A board, as described in Section 315, may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

Assembly Bill No. 1414

CHAPTER 76

An act to amend Section 11055 of the Health and Safety Code, relating to controlled substances.

[Approved by Governor July 15, 2010. Filed with Secretary of State July 15, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1414, Hill. Controlled substances: apomorphine: unscheduled.

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law places apomorphine within Schedule II.

This bill would remove apomorphine from Schedule II of the California Uniform Controlled Substances Act and make it an unscheduled substance.

The people of the State of California do enact as follows:

SECTION 1. Section 11055 of the Health and Safety Code is amended to read:

11055. (a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

- (A) Raw opium.
- (B) Opium extracts.
- (C) Opium fluid extracts.
- (D) Powdered opium.
- (E) Granulated opium.
- (F) Tincture of opium.
- (G) Codeine.
- (H) Ethylmorphine.
- (I) Hydrocodone.

- (J) Hydromorphone.
 - (K) Metopon.
 - (L) Morphine.
 - (M) Oxycodone.
 - (N) Oxymorphone.
 - (O) Thebaine.
- (2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.
- (3) Opium poppy and poppy straw.
- (4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.
- (5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).
- (6) Cocaine, except as specified in Section 11054.
- (7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
- (c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:
- (1) Alfentanyl.
 - (2) Alphaprodine.
 - (3) Anileridine.
 - (4) Bezitramide.
 - (5) Bulk dextropropoxyphene (nondosage forms).
 - (6) Dihydrocodeine.
 - (7) Diphenoxylate.
 - (8) Fentanyl.
 - (9) Isomethadone.
 - (10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).
 - (11) Levomethorphan.
 - (12) Levorphanol.
 - (13) Metazocine.
 - (14) Methadone.
 - (15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
 - (16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
 - (17) Pethidine (meperidine).

- (18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
- (19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
- (20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- (21) Phenazocine.
- (22) Piminodine.
- (23) Racemethorphan.
- (24) Racemorphan.
- (25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

- (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
- (2) Methamphetamine, its salts, isomers, and salts of its isomers.
- (3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.
- (4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.
- (5) Phenmetrazine and its salts.
- (6) Methylphenidate.
- (7) Khat, which includes all parts of the plant classified botanically as *Catha Edulis*, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.
- (8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Amobarbital.
- (2) Pentobarbital.
- (3) Phencyclidines, including the following:
 - (A) 1-(1-phenylcyclohexyl) piperidine (PCP).
 - (B) 1-(1-phenylcyclohexyl) morpholine (PCM).
 - (C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph.

The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted,

submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone. Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

Assembly Bill No. 1659

CHAPTER 666

An act to add Article 7.5 (commencing with Section 9147.7) to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code, relating to state government.

[Approved by Governor September 30, 2010. Filed with
Secretary of State September 30, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1659, Huber. State government: agency repeals.

Existing law establishes the Joint Committee on Boards, Commissions, and Consumer Protection and, until January 1, 2012, requires the committee to hold public hearings at specified times and to evaluate whether a board or regulatory program has demonstrated a need for its continued existence. Existing law states the intent of the Legislature that all existing and proposed state boards be subject to review every 4 years to evaluate and determine whether each has demonstrated a public need for its continued existence, as specified.

This bill would create the Joint Sunset Review Committee to identify and eliminate waste, duplication, and inefficiency in government agencies and to conduct a comprehensive analysis of every "eligible agency," as defined, to determine if the agency is still necessary and cost effective. The bill would define an "eligible agency" as an entity of state government, however denominated, for which a date for repeal has been established by statute on or after January 1, 2011. The bill would require each eligible agency scheduled for repeal to submit a report to the committee containing specified information. The bill would require the committee to take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed, and would require that an eligible agency be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the agency. The bill would specify the composition of the committee, which would be appointed by the Senate Committee on Rules and the Speaker of the Assembly, and certain aspects of its operating procedure.

The people of the State of California do enact as follows:

SECTION 1. Article 7.5 (commencing with Section 9147.7) is added to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code, to read:

Article 7.5. Sunset Review

9147.7. (a) For the purpose of this section, “eligible agency” means any agency, authority, board, bureau, commission, conservancy, council, department, division, or office of state government, however denominated, excluding an agency that is constitutionally created or an agency related to postsecondary education, for which a date for repeal has been established by statute on or after January 1, 2011.

(b) The Joint Sunset Review Committee is hereby created to identify and eliminate waste, duplication, and inefficiency in government agencies. The purpose of the committee is to conduct a comprehensive analysis over 15 years, and on a periodic basis thereafter, of every eligible agency to determine if the agency is still necessary and cost effective.

(c) Each eligible agency scheduled for repeal shall submit to the committee, on or before December 1 prior to the year it is set to be repealed, a complete agency report covering the entire period since last reviewed, including, but not limited to, the following:

- (1) The purpose and necessity of the agency.
- (2) A description of the agency budget, priorities, and job descriptions of employees of the agency.
- (3) Any programs and projects under the direction of the agency.
- (4) Measures of the success or failures of the agency and justifications for the metrics used to evaluate successes and failures.
- (5) Any recommendations of the agency for changes or reorganization in order to better fulfill its purpose.

(d) The committee shall take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed. An eligible agency shall be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the eligible agency. No eligible agency shall be extended in perpetuity unless specifically exempted from the provisions of this section. The committee may recommend that the Legislature extend the statutory sunset date for no more than one year to allow the committee more time to evaluate the eligible agency.

(e) The committee shall be comprised of 10 members of the Legislature. The Senate Committee on Rules shall appoint five members of the Senate to the committee, not more than three of whom shall be members of the same political party. The Speaker of the Assembly shall appoint five members of the Assembly to the committee, not more than three of whom shall be members of the same political party. Members shall be appointed within 15 days after the commencement of the regular session. Each member of the committee who is appointed by the Senate Committee on Rules or the Speaker of the Assembly shall serve during that committee member’s term of office or until that committee member no longer is a Member of the Senate or the Assembly, whichever is applicable. A vacancy on the committee shall be filled in the same manner as the original appointment. Three Assembly Members and three Senators who are members of the committee shall constitute a quorum for the conduct of committee business.

Members of the committee shall receive no compensation for their work with the committee.

(f) The committee shall meet not later than 30 days after the first day of the regular session to choose a chairperson and to establish the schedule for eligible agency review provided for in the statutes governing the eligible agencies. The chairperson of the committee shall alternate every two years between a Member of the Senate and a Member of the Assembly, and the vice chairperson of the committee shall be a member of the opposite house as the chairperson.

(g) This section shall not be construed to change the existing jurisdiction of the budget or policy committees of the Legislature.

Assembly Bill No. 2130

CHAPTER 670

An act to amend Section 22 of, to repeal Section 101.1 of, and to repeal Division 1.2 (commencing with Section 473) of, the Business and Professions Code, to amend and repeal Section 4351 of the Food and Agricultural Code, to amend Sections 9148.51 and 9148.52 of, and to amend and repeal Sections 8164.1, 8164.2, and 8164.3 of, the Government Code, to amend and repeal Sections 1777, 1777.2, and 1777.4 of the Health and Safety Code, and to amend and repeal Sections 5073.5, 5073.7, and 5074 of the Public Resources Code, relating to professions and vocations.

[Approved by Governor September 30, 2010. Filed with
Secretary of State September 30, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2130, Huber. Professions and vocations: sunset review.

Existing law establishes the Joint Committee on Boards, Commissions, and Consumer Protection and, until January 1, 2012, requires the committee to hold public hearings at specified times and to evaluate whether a board or regulatory program has demonstrated a need for its continued existence. Existing law states the intent of the Legislature that all existing and proposed state boards be subject to review every 4 years to evaluate and determine whether each has demonstrated a public need for its continued existence, as specified.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection and make other conforming changes.

The bill would instead require the Joint Sunset Review Committee to review all eligible agencies, as specified. The bill would require the committee to evaluate and make a report on whether an agency should be terminated or its functions revised or consolidated. The bill would require that the report shall be available to the public and the Legislature, as specified. The bill would impose a sunset date of January 1, 2013, on the State Race Track Leasing Commission, the Capitol Area Committee, the Continuing Care Advisory Committee, and the California Recreational Trails Committee.

The bill would provide that its provisions would not become operative unless AB 1659 of the 2009–10 Regular Session is enacted and establishes the Joint Sunset Review Committee.

The people of the State of California do enact as follows:

SECTION 1. Section 22 of the Business and Professions Code is amended to read:

22. "Board," as used in any provision of this code, refers to the board in which the administration of the provision is vested, and unless otherwise expressly provided, shall include "bureau," "commission," "committee," "department," "division," "examining committee," "program," and "agency."

SEC. 2. Section 101.1 of the Business and Professions Code is repealed.

SEC. 3. Division 1.2 (commencing with Section 473) of the Business and Professions Code is repealed.

SEC. 4. Section 4351 of the Food and Agricultural Code is amended to read:

4351. (a) There is hereby created the State Race Track Leasing Commission which shall be composed of the Director of Food and Agriculture, the Director of Finance, and the Director of General Services and three individuals, appointed by the Governor, who are members of the Board of Directors of the 22nd District Agricultural Association. The Director of Finance shall serve as chairperson of the commission. All meetings of the commission shall be open and public.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 5. Section 8164.1 of the Government Code is amended to read:

8164.1. There is in state government a Capitol Area Committee consisting of nine members who shall be appointed in the following manner:

(a) Four members of the committee shall be appointed by the Governor of which at least one member shall be appointed from a list of three candidates submitted by the City of Sacramento and at least one member shall be appointed from a list of three candidates submitted by the County of Sacramento. Two members shall be appointed for a term expiring December 31, 1979, and two for a term expiring December 31, 1981.

(b) Two members shall be appointed by the Speaker of the Assembly, one of whom may be a Member of the Assembly, and two members shall be appointed by the Senate Rules Committee, one of whom may be a Member of the Senate. Legislative members of the committee shall meet and, except as otherwise provided by the Constitution, advise the department to the extent that the advisory participation is not incompatible with their respective positions as Members of the Legislature. Of the four appointments by the Legislature, two shall be appointed for a term expiring December 31, 1979, and two for a term expiring December 31, 1981.

(c) One shall be appointed by and serve at the pleasure of the director.

Subsequent appointments pursuant to subdivisions (a) and (b) shall be for terms of four years, ending on December 31st of the fourth year after the end of the prior term, except that appointments to fill vacancies occurring for any reason other than the expiration of the term shall be for the unexpired

portion of the term in which they occur. The members of the board shall hold office until their successors are appointed and qualify.

The members of the committee shall not receive compensation from the state for their services under this article but, when called to attend a meeting of the committee, shall be reimbursed for their actual and necessary expenses incurred in connection with the meeting in accordance with the rules of the Department of Personnel Administration.

(d) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 6. Section 8164.2 of the Government Code is amended to read:

8164.2. (a) The committee shall elect a chairperson. The committee shall meet at least quarterly or upon the call of the chairperson or the written request of any three members.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 7. Section 8164.3 of the Government Code is amended to read:

8164.3. (a) It is the purpose of the committee to independently review the reports of the department to the Legislature and counsel and advise the department in the carrying out of its responsibilities related to the Capitol Area Plan. The committee may submit separate comments on the departmental reports on the Capitol Area Plan to the Legislature. The committee shall involve a broad cross section of interested citizens in the form of an advisory body. The advisory body shall serve without compensation.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 8. Section 9148.51 of the Government Code is amended to read:

9148.51. (a) It is the intent of the Legislature that all existing and proposed eligible agencies, as defined in subdivision (a) of Section 9147.7, be subject to review to evaluate and determine whether each has demonstrated a public need for its continued existence in accordance with enumerated factors and standards as set forth in Article 7.5 (commencing with Section 9147.7).

(b) If any state board becomes inoperative or is repealed in accordance with the act that added this section, any provision of existing law that provides for the appointment of board members and specifies the qualifications and tenure of board members shall not be implemented and shall have no force or effect while that state board is inoperative or repealed.

(c) Any provision of law authorizing the appointment of an executive officer by a state board subject to the review described in Article 7.5 (commencing with Section 9147.7), or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable state board is inoperative or repealed.

SEC. 9. Section 9148.52 of the Government Code is amended to read:

9148.52. (a) The Joint Sunset Review Committee established pursuant to Section 9147.7 shall review all eligible agencies.

(b) The committee shall evaluate and make determinations pursuant to Article 7.5 (commencing with Section 9147.7).

(c) Pursuant to an evaluation made as specified in this section, the committee shall make a report which shall be available to the public and the Legislature on whether an agency should be terminated, or continued, or whether its functions should be revised or consolidated with those of another agency, and include any other recommendations as necessary to improve the effectiveness and efficiency of the agency. If the committee deems it advisable, the report may include proposed legislative proposals that would carry out its recommendations.

SEC. 10. Section 1777 of the Health and Safety Code is amended to read:

1777. (a) The Continuing Care Advisory Committee of the department shall act in an advisory capacity to the department on matters relating to continuing care contracts.

(b) The members of the committee shall include:

(1) Three representatives of nonprofit continuing care providers pursuant to this chapter, each of whom shall have offered continuing care services for at least five years prior to appointment. One member shall represent a multifacility provider and shall be appointed by the Governor in even years. One member shall be appointed by the Senate Committee on Rules in odd years. One member shall be appointed by the Speaker of the Assembly in odd years.

(2) Three senior citizens who are not eligible for appointment pursuant to paragraphs (1) and (4) who shall represent consumers of continuing care services, all of whom shall be residents of continuing care retirement communities but not residents of the same provider. One senior citizen member shall be appointed by the Governor in even years. One senior citizen member shall be appointed by the Senate Committee on Rules in odd years. One senior citizen member shall be appointed by the Speaker of the Assembly in odd years.

(3) A certified public accountant with experience in the continuing care industry, who is not a provider of continuing care services. This member shall be appointed by the Governor in even years.

(4) A representative of a for-profit provider of continuing care contracts pursuant to this chapter. This member shall be appointed by the Governor in even years.

(5) An actuary. This member shall be appointed by the Governor in even years.

(6) One representative of residents of continuing care retirement communities appointed by the senior citizen representatives on the committee.

(7) One representative of either nonprofit or for-profit providers appointed by the representatives of nonprofit and for-provider providers on the committee.

(c) Commencing January 1, 1997, all members shall serve two-year terms and be appointed based on their interest and expertise in the subject area. The Governor shall designate the chairperson for the committee with the advice and consent of the Senate. A member may be reappointed at the pleasure of the appointing power. The appointing power shall fill all vacancies on the committee within 60 days. All members shall continue to serve until their successors are appointed and qualified.

(d) The members of the committee shall serve without compensation, except that each member shall be paid from the Continuing Care Provider Fee Fund a per diem of twenty-five dollars (\$25) for each day's attendance at a meeting of the committee not to exceed six days in any month. The members of the committee shall also receive their actual and necessary travel expenses incurred in the course of their duties. Reimbursement of travel expenses shall be at rates not to exceed those applicable to comparable state employees under Department of Personnel Administration regulations.

(e) Prior to commencement of service, each member shall file with the department a statement of economic interest and a statement of conflict of interest pursuant to Article 3 (commencing with Section 87300) of the Government Code.

(f) If, during the period of appointment, any member no longer meets the qualifications of subdivision (b), that member shall submit his or her resignation to their appointing power and a qualified new member shall be appointed by the same power to fulfill the remainder of the term.

(g) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 11. Section 1777.2 of the Health and Safety Code is amended to read:

1777.2. (a) The Continuing Care Advisory Committee shall:

(1) Review the financial and managerial condition of continuing care retirement communities operating under a certificate of authority.

(2) Review the financial condition of any continuing care retirement community that the committee determines is indicating signs of financial difficulty and may be in need of close supervision.

(3) Monitor the condition of those continuing care retirement communities that the department or the chair of the committee may request.

(4) Make available consumer information on the selection of continuing care contracts and necessary contract protections in the purchase of continuing care contracts.

(5) Review new applications regarding financial, actuarial, and marketing feasibility as requested by the department.

(b) The committee shall make recommendations to the department regarding needed changes in its rules and regulations and upon request provide advice regarding the feasibility of new continuing care retirement communities and the correction of problems relating to the management or operation of any continuing care retirement community. The committee

shall also perform any other advisory functions necessary to improve the management and operation of continuing care retirement communities.

(c) The committee may report on its recommendations directly to the director of the department.

(d) The committee may hold meetings, as deemed necessary to the performance of its duties.

(e) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 12. Section 1777.4 of the Health and Safety Code is amended to read:

1777.4. (a) Any member of the Continuing Care Advisory Committee is immune from civil liability based on acts performed in his or her official capacity. Costs of defending civil actions brought against a member for acts performed in his or her official capacity shall be borne by the complainant. However, nothing in this section immunizes any member for acts or omissions performed with malice or in bad faith.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 13. Section 5073.5 of the Public Resources Code is amended to read:

5073.5. (a) The Governor shall establish a California Recreational Trails Committee to advise the director in the development and coordination of the system. The committee shall consist of seven members appointed by the Governor. Two members shall be selected from the northern, two members from the southern, and two members from the central portions of the state, and one member shall be selected at large. Members shall be selected from lists submitted by private organizations that have a demonstrated interest in the establishment of recreation trails. The chair of the committee shall be elected by the members from their membership.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 14. Section 5073.7 of the Public Resources Code is amended to read:

5073.7. (a) The terms of the members of the committee shall be four years, except that such members first appointed to the committee shall classify themselves by lot so that the term of three members shall expire January 15, 1976, the term of two members shall expire January 15, 1977, and the term of two members shall expire January 15, 1978.

Members of the committee shall serve without compensation, but shall be reimbursed for actual and necessary expenses, including traveling expenses, incurred in the performance of their duties.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 15. Section 5074 of the Public Resources Code is amended to read: 5074. The committee shall have the following powers and duties:

(a) Coordinate trail planning and development among cities, counties, and districts. In carrying out this responsibility, the committee shall review records of easements and other interests in lands which are available for recreational trail usage, including public lands, utility easements, other rights-of-way, gifts, or surplus public lands which may be adaptable for such use, and shall advise the director in the development of standards for trail construction so that uniform construction standards may be available to cities, counties, and districts.

(b) Advise the director in the preparation and maintenance of the plan.

(c) Study the problems and opportunities presented by the use of private property for recreational trail use and advise the director on measures to mitigate undesirable aspects of such usage.

(d) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 16. The provisions of this act shall not become operative unless Assembly Bill 1659 of the 2009–10 Regular Session is also enacted and becomes operative on or before January 1, 2011, and adds Article 7.5 (commencing with Section 9147.7) to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code to establish the Joint Sunset Review Committee.

Assembly Bill No. 1701

CHAPTER 667

An act to amend Section 4145 of the Business and Professions Code, and to amend Section 11364 of the Health and Safety Code, relating to public health.

[Approved by Governor September 30, 2010. Filed with Secretary of State September 30, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1701, Chesbro. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is generally required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

Existing law, until December 31, 2010, authorizes a city or county to authorize a licensed pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project. Existing law prohibits the possession and sale of drug paraphernalia, but until December 31, 2010, allows a person, if authorized by a city or county, to possess 10 or fewer hypodermic needles or syringes if acquired through an authorized source.

This bill would delete the December 31, 2010, end dates for these authorizations and would reestablish these authorizations until December 31, 2018.

This bill would not become operative if SB 1029 of the 2009–10 Regular Session, amending Section 4145 of the Business and Professions Code and amending Section 11364 of the Health and Safety Code, is enacted and takes effect on or before January 1, 2011.

The people of the State of California do enact as follows:

SECTION 1. Section 4145 of the Business and Professions Code is amended to read:

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need

requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2018, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered with the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

SEC. 2. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2018, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

SEC. 3. This act shall not become operative if Senate Bill 1029 of the 2009–10 Regular Session, amending Section 4145 of the Business and Professions Code and amending Section 11364 of the Health and Safety Code, is enacted and takes effect on or before January 1, 2011.

Senate Bill No. 700

CHAPTER 505

An act to amend Sections 800, 803.1, 805, 805.1, 805.5, 2027, and 2220 of, and to add Section 805.01 to, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 29, 2010. Filed with Secretary of State September 29, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

SB 700, Negrete McLeod. Healing arts: peer review.

Existing law provides for the professional review of specified healing arts licentiates through a peer review process.

This bill would define the term "peer review" for purposes of those provisions.

Under existing law, specified persons are required to file a report, designated as an "805 report," with a licensing board within 15 days after a specified action is taken against a person licensed by that board.

This bill would also require specified persons to file a report with a licensing board within 15 days after a peer review body makes a decision or recommendation regarding the disciplinary action to be taken against a licentiate of that board based on the peer review body's determination, following formal investigation, that the licentiate may have engaged in various acts, including incompetence, substance abuse, excessive prescribing or furnishing of controlled substances, or sexual misconduct, among other things. The bill would authorize the board to inspect and copy certain documents in the record of that investigation.

Existing law requires the board to maintain an 805 report for a period of 3 years after receipt.

This bill would require the board to maintain the report electronically.

Existing law authorizes the Medical Board of California, the Osteopathic Medical Board of California, and the Dental Board of California to inspect and copy certain documents in the record of any disciplinary proceeding resulting in action that is required to be reported in an 805 report.

This bill would specify that the boards have the authority to also inspect, as permitted by other applicable law, any certified copy of medical records in the record of the disciplinary proceeding.

Existing law requires specified healing arts boards to maintain a central file of their licensees containing, among other things, disciplinary information reported through 805 reports.

Under this bill, if a court finds, in a final judgment, that the peer review resulting in the 805 report was conducted in bad faith and the licensee who

Attachment A-3

Vetoed Legislation

With Veto Messages

AB 1858 (Blumenfield) – Hypodermic Needles & Syringes

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

AB 2747 (Lowenthal) – Prisoners: Pharmacy Services

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Produces

SB 1029 (Yee) – Hypodermic Needles & Syringes

BILL NUMBER: AB 1858
VETOED DATE: 09/30/2010

To the Members of the California State Assembly:
I am returning Assembly Bill 1858 without my signature.
I signed legislation in 2005 that reflected a careful balance between good public health policy and local decision-making authority. I remain comfortable with that original decision and do not believe it is appropriate to change this balance and instead give authority to the state Department of Public Health to overrule local decisions regarding syringe exchange programs.
For this reason, I am unwilling to sign this bill.
Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 1858

Passed the Assembly August 26, 2010

Chief Clerk of the Assembly

Passed the Senate August 24, 2010

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend, repeal, and add Sections 121349, 121349.1, 121349.2, and 121349.3 of, and to add and repeal Section 121349.4 to, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1858, Blumenfield. Hypodermic needles and syringes: exchange services.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes, and requires, with certain exceptions, a prescription to purchase a hypodermic needle or syringe for human use. Existing law prohibits any person from possessing or having under his or her control any hypodermic needle or syringe, except in accordance with those regulatory provisions.

Existing law authorizes a clean needle and syringe exchange project in any city and county, county, or city, as specified.

This bill would, until January 1, 2016, permit the State Department of Public Health to authorize certain entities, that meet prescribed conditions, to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infection spread through the sharing of used hypodermic needles and syringes. The bill, until January 1, 2016, would require the entities to submit an application to the department, would require a 45-day public comment period, would specify that participants shall not be subject to criminal prosecution for possession of needles and syringes acquired under the program, and would make conforming changes.

The bill would also, until January 1, 2016, require the department to establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services. The bill would, until January 1, 2016, change related hearing requirements from annually to biennially. The bill would, until January 1, 2016, require the department to report to certain committees of the Legislature, as prescribed.

The people of the State of California do enact as follows:

SECTION 1. Section 121349 of the Health and Safety Code is amended to read:

121349. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other provision of law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), apply for authorization under this chapter, and have sufficient staff and capacity to provide services as described in Section 121349.1, as determined by the department, to provide hypodermic needle and syringe exchange services consistent with state and federal standards, including those of the United States Public Health Service, in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infection spread through the sharing of used hypodermic needles and syringes.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter by the State Department of Public Health, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, any of the following services:

- (A) Drug abuse treatment services.
- (B) HIV or hepatitis C screening.
- (C) Hepatitis A and hepatitis B vaccination.
- (D) Screening for sexually transmitted infections.
- (E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.
- (F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

- (A) Provide needles and syringe exchange services for all of its participants.
- (B) Provide HIV and viral hepatitis prevention education services for all of its participants.
- (C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

- (A) The total number of persons served.
- (B) The total number of syringes and needles distributed, recovered, and disposed of.
- (C) The total numbers and types of referrals to drug treatment and other services.

(5) If the application is provisionally deemed appropriate by the State Department of Public Health the department shall, at least 45 days prior to approval of the application, provide for a period of public comment as follows:

- (A) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.
- (B) Send a written and an electronic mail notice to the local public health officer of the affected jurisdiction.
- (e) The State Department of Public Health shall establish and maintain on its Internet Web site the address and contact

information of programs providing hypodermic needle and syringe exchange services pursuant to subdivision (c).

(f) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(g) This section shall become inoperative on January 1, 2016, and as of that date is repealed.

SEC. 2. Section 121349 is added to the Health and Safety Code, to read:

121349. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to attempt to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(d) This section shall become operative on January 1, 2016.

SEC. 3. Section 121349.1 of the Health and Safety Code is amended to read:

121349.1. (a) The State Department of Public Health, or a city and county, or a county, or a city with or without a health department, in consultation with the State Department of Public Health, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Public Health Service, subject to the availability of

funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes acquired from an authorized needle and syringe exchange project entity.

(b) This section shall become inoperative on January 1, 2016, and as of that date is repealed.

SEC. 4. Section 121349.1 is added to the Health and Safety Code, to read:

121349.1. (a) A city and county, or a county, or a city with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Providers participating in an exchange project authorized by the county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for possession of needles or syringes during participation in an exchange project.

(b) This section shall become operative on January 1, 2016.

SEC. 5. Section 121349.2 of the Health and Safety Code is amended to read:

121349.2. (a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become inoperative on January 1, 2016, and as of that date is repealed.

SEC. 6. Section 121349.2 is added to the Health and Safety Code, to read:

121349.2. (a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on an annual basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become operative on January 1, 2016.

SEC. 7. Section 121349.3 of the Health and Safety Code is amended to read:

121349.3. (a) The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of the local health officer.

(b) This section shall become inoperative on January 1, 2016, and as of that date is repealed.

SEC. 8. Section 121349.3 is added to the Health and Safety Code, to read:

121349.3. (a) The health officer of the participating jurisdiction shall present annually at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these

programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate.

(b) This section shall become operative on January 1, 2016.

SEC. 9. Section 121349.4 is added to the Health and Safety Code, to read:

121349.4. (a) Notwithstanding Sections 9795 and 10231.5 of the Government Code, the State Department of Public Health shall, commencing not later than November 1, 2014, submit to the Senate Committee on Budget and Fiscal Review, and Assembly Committee on Budget, the Senate and the Assembly Committees on Health, and the Joint Legislative Budget Committee, all biennial reports made to open meetings of county boards of supervisors or city councils pursuant to Section 121349.2, and the number and location of all programs authorized by the department since January 1, 2011.

(b) This section shall remain in effect only until January 1, 2016, and as of that date is repealed.

Approved _____, 2010

Governor

BILL NUMBER: AB 2077
VETOED DATE: 09/29/2010

To the Members of the California State Assembly:

I am returning Assembly Bill 2077 without my signature.

This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California.

For these reasons, I am unable to sign this bill.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 2077

Passed the Assembly August 27, 2010

Chief Clerk of the Assembly

Passed the Senate August 24, 2010

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital

pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a “manufacturer” does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill’s requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. The Legislature makes the following findings and declarations:

(a) Hospitals have been encouraged to move toward the use of automation and bedside barcode checking to improve the safety and efficiency of drug distribution and administration to patients. For many hospitals, the technology to enable them to achieve this patient-safety goal is cost prohibitive.

(b) Many drugs received from manufacturers are not in the proper unit dose for immediate administration to patients, and are not barcoded. As a result, individual hospitals must locally prepare and package these drugs or contract with a packager, that is not licensed by either the California State Board of Pharmacy or managed by a pharmacist-in-charge who is licensed by the California State Board of Pharmacy, to do so.

(c) The Business and Professions Code definition of drug “manufacturer” allows one hospital pharmacy to compound and package medications for another hospital only for specific patients, without being licensed as a manufacturer. This restriction does not

support the most current hospital drug distribution processes, nor does it accommodate innovations that will improve patient safety.

(d) Centralization of the packaging operations as a licensed pharmacy under the license of a hospital, rather than as a “manufacturer,” ensures the patient-safety oversight of the California State Board of Pharmacy and other hospital regulatory and accreditation bodies, and adherence to the new stronger pharmacy compounding regulations.

SEC. 2. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) “Hospital pharmacy” means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital, in either another physical plant on the same premises or on a separate premises, located within a 100 mile radius of the hospital, that is regulated under a hospital’s license. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) Any unit-dose medication produced by a hospital pharmacy under common ownership, as described in Section 4033, shall be barcoded to be readable at the patient’s bedside.

(d) A hospital pharmacy may prepare and store a limited quantity of unit-dose medications in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of patients of the hospital based on a documented history of prescriptions for that patient population.

(e) Nothing in this section shall obviate the obligation of a hospital pharmacy, hospital, or pharmacist to comply with all applicable federal and state laws.

SEC. 3. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) “Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the

immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for the purpose of dispensing or administering the drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change.

(3) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy that, at a patient’s request, repackages a drug previously dispensed to the patient, or to the patient’s agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer” means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer’s third-party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer’s affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of

the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2010

Governor

BILL NUMBER: AB 2747
VETOED DATE: 09/30/2010

To the Members of the California State Assembly:

I am returning Assembly Bill (AB) 2747 without my signature.

This bill requires the California Department of Corrections and Rehabilitation (CDCR) to maintain and operate a comprehensive pharmacy services program for facilities under its jurisdiction, as specified, and authorizes CDCR to operate and maintain a Centralized Pharmacy Distribution Center (CPDC). Additionally, AB 2747 requires CDCR to report specified information to legislative committees relating to its pharmaceutical costs and operation of a fully functioning and centralized pharmacy center.

CDCR is currently under federal receivership for its health care services. The Receiver has the authority to conduct the provisions of AB 2747 and is currently in the process of implementing the CPDC. It would be premature for me to sign a bill when the successfulness of the CPDC has yet to be determined.

For these reasons, I am unable to sign this bill.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 2747

Passed the Assembly August 24, 2010

Chief Clerk of the Assembly

Passed the Senate August 23, 2010

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add Section 5024.2 to the Penal Code, relating to prisoners.

LEGISLATIVE COUNSEL'S DIGEST

AB 2747, Bonnie Lowenthal. Prisoners: pharmacy services.

Existing law provides that it is the intent of the Legislature that the Department of Corrections and Rehabilitation, in cooperation with the Department of General Services and other appropriate state agencies, take prompt action to adopt cost-effective reforms in its drug and medical supply procurement processes, as specified. Existing law authorizes the Secretary of the Department of Corrections and Rehabilitation to adopt regulations requiring manufacturers of drugs to pay the department a rebate for the purchase of drugs for offenders in state custody that is at least equal to the rebate that would be applicable to the drugs under the federal Social Security Act.

This bill would provide that the Department of Corrections and Rehabilitation shall maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that incorporates, among other things, a statewide pharmacy administration system with direct authority and responsibility for program oversight and a multidisciplinary, statewide Pharmacy and Therapeutics Committee with specified responsibilities. The bill would authorize the department to operate and maintain a centralized pharmacy distribution center, as specified. The bill would authorize the department to investigate and initiate potential systematic improvements in order to provide for the safe and efficient distribution and control of, and accountability for, drugs within the department's system. The bill would require the department to ensure that there is a program providing for the regular inspection of all the department's pharmacies to verify compliance with applicable rules, regulations, and other standards, as specified. The bill would require the department to report specified information to specified legislative committees relating to its pharmaceutical costs and its operation of a fully functioning and centralized pharmacy distribution center.

The people of the State of California do enact as follows:

SECTION 1. Section 5024.2 is added to the Penal Code, to read:

5024.2. (a) The Department of Corrections and Rehabilitation shall maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that, at a minimum, incorporates all of the following:

(1) A statewide pharmacy administration system with direct authority and responsibility for program administration and oversight.

(2) Medically necessary pharmacy services using professionally and legally qualified pharmacists, consistent with the size and the scope of medical services provided.

(3) Written procedures and operational practices pertaining to the delivery of pharmaceutical services.

(4) A multidisciplinary, statewide Pharmacy and Therapeutics Committee responsible for all of the following:

(A) Developing and managing a department formulary.

(B) Standardizing the strengths and dosage forms for medications used in department facilities.

(C) Maintaining and monitoring a system for the review and evaluation of corrective actions related to errors in prescribing, dispensing, and administering medications.

(D) Conducting regular therapeutic category reviews for medications listed in the department formulary.

(E) Evaluating medication therapies and providing input to the development of disease management guidelines used in the department.

(5) A requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

(6) Use of an enterprise-based pharmacy operating system that provides management with information on prescription workloads, medication utilization, prescribing data, and other key pharmacy information.

(b) The department is authorized to operate and maintain a centralized pharmacy distribution center to provide advantages of scale and efficiencies related to medication purchasing, inventory control, volume production, drug distribution, workforce utilization,

and increased patient safety. The centralized pharmacy distribution center and institutional pharmacies shall be licensed as pharmacies by the California State Board of Pharmacy and shall meet all applicable regulations applying to a pharmacy.

(1) The centralized pharmacy distribution center shall include systems to do all of the following:

(A) Order and package bulk pharmaceuticals and prescription and stock orders for all department correctional facilities.

(B) Label medications as required to meet state and federal prescription requirements.

(C) Provide barcode validation matching the drug to the specific prescription or floor stock order.

(D) Sort completed orders for shipping and delivery to department facilities.

(2) Notwithstanding any other requirements, the department centralized pharmacy distribution center is authorized to do the following:

(A) Package bulk pharmaceuticals into both floor stock and patient-specific packs.

(B) Reclaim, for reissue, unused and unexpired medications.

(C) Distribute the packaged products to department facilities for use within the state corrections system.

(3) The centralized pharmacy distribution center shall maintain a system of quality control checks on each process used to package, label, and distribute medications. The quality control system shall include a regular process of random checks by a licensed pharmacist.

(c) The department may investigate and initiate potential systematic improvements in order to provide for the safe and efficient distribution and control of, and accountability for, drugs within the department's statewide pharmacy administration system, taking into account factors unique to the correctional environment.

(d) The department shall ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable law, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients. Corrective actions necessary to resolve any discrepancies or deficiencies shall be documented in writing and monitored by the department for compliance.

(e) On March 1, 2012, and each March 1 thereafter, the department shall report all of the following to the Joint Legislative Budget Committee, the Senate Committee on Appropriations, the Senate Committee on Budget and Fiscal Review, the Senate Committee on Health, the Senate Committee on Public Safety, the Assembly Committee on Appropriations, the Assembly Committee on Budget, the Assembly Committee on Health, and the Assembly Committee on Public Safety:

(1) The extent to which the Pharmacy and Therapeutics Committee has achieved the objectives set forth in this section, as well as the most significant reasons for achieving or not achieving those objectives.

(2) The extent to which the department is achieving the objective of operating a fully functioning and centralized pharmacy distribution center, as set forth in this section, that distributes pharmaceuticals to every adult prison under the jurisdiction of the department, as well as the most significant reasons for achieving or not achieving that objective.

(3) The extent to which the centralized pharmacy distribution center is achieving cost savings through improved efficiency and distribution of unit dose medications.

(4) A description of planned or implemented initiatives to accomplish the next 12 months' objectives for achieving the goals set forth in this section, including a fully functioning and centralized pharmacy distribution center that distributes pharmaceuticals to every adult facility under the jurisdiction of the department.

(5) The costs for prescription pharmaceuticals for the previous fiscal year, both statewide and at each adult prison under the jurisdiction of the department, and a comparison of these costs with those of the prior fiscal year.

(f) The requirement for submitting a report imposed under subdivision (e) is inoperative on March 1, 2016, pursuant to Section 10231.5 of the Government Code.

Approved _____, 2010

Governor

BILL NUMBER: SB 971
VETOED DATE: 09/29/2010

To the Members of the California State Senate:
I am returning Senate Bill 971 without my signature.
This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address.
For these reasons, I am unable to sign this bill.
Sincerely,

Arnold Schwarzenegger

Senate Bill No. 971

Passed the Senate August 25, 2010

Secretary of the Senate

Passed the Assembly August 16, 2010

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add Article 5 (commencing with Section 125286.1) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic disease services.

LEGISLATIVE COUNSEL'S DIGEST

SB 971, Pavley. Bleeding disorders: blood clotting products.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

The people of the State of California do enact as follows:

SECTION 1. Article 5 (commencing with Section 125286.1) is added to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.1. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.2. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors have provided people with hemophilia and other bleeding disorders with the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.3. Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) “Assay” means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) “Ancillary infusion equipment and supplies” means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) “Bleeding disorder” means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called “factors,” including all forms of hemophilia and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting without treatment.

(d) “Blood clotting product” means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) “Emergency” means care as defined in Section 1317.1.

(f) “Hemophilia” means a human bleeding disorder caused by a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) “Hemophilia treatment center” means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) “Home nursing services” means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.

(i) “Home use” means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(j) “Patient” means a person needing a blood clotting product for home use.

(k) (1) “Provider of blood clotting products for home use” means all the following pharmacies, except as described in Section 125286.6, that dispense blood clotting factors for home use:

- (A) Hospital pharmacies.
- (B) Health system pharmacies.
- (C) Pharmacies affiliated with hemophilia treatment centers.
- (D) Specialty home care pharmacies.
- (E) Retail pharmacies.

(2) The providers described in this subdivision may also provide home nursing services for persons with bleeding disorders.

(3) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.4. Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.

(c) Have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human

plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) When home nursing services are necessary, as determined by the treating physician, provide these services either directly or through a qualified third party with experience in treating bleeding disorders and coordinate pharmacy services with the third party when one is used to provide home nursing services.

(h) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(i) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, medications, and home nursing services to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(j) Maintain 24-hour on call service seven days a week for every day of the year, adequately screen phone calls for emergencies, and acknowledge all phone calls within one hour or less.

(k) Provide patients who have ordered their products with a designated contact phone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(l) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(m) Provide language interpretive services over the phone or in person, as needed by the patient.

(n) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(o) Provide the patient with a sharps container and instructions on how to dispose of medical waste sharps. However, the provider of blood clotting products shall not be liable for any acts or omissions of the patient in the handling and disposal of medical waste.

(p) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(q) Comply with the privacy and confidentiality requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.5. The California State Board of Pharmacy shall administer and enforce this article.

125286.6. Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

Approved _____, 2010

Governor

BILL NUMBER: SB 1029
VETOED DATE: 09/30/2010

To the Members of the California State Senate:
I am returning Senate Bill 1029 without my signature.
When I signed legislation my first year in office allowing for a pilot program to allow the sale of syringes through participating counties and registered pharmacies, I was seeking to balance the competing public health, law enforcement and local control issues that this issue requires. I believe this balance was achieved and SB 1029 would remove the ability of local officials to best determine policies in their jurisdiction. Some counties have not sought to implement this pilot program, citing competing priorities, lack of pharmacy interest and law enforcement opposition.
I respect these local decisions and while I appreciate the author's hard work and dedication to this issue, I cannot sign this bill.
Sincerely,

Arnold Schwarzenegger

Senate Bill No. 1029

Passed the Senate August 31, 2010

Secretary of the Senate

Passed the Assembly August 26, 2010

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 4145 and 4148 of, and to repeal Section 4140 of, the Business and Professions Code, and to amend Section 11364 of, to add Section 121281 to, and to repeal Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1029, Yee. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes, and requires, with certain exceptions, a prescription to purchase a hypodermic needle or syringe for human use. Existing law prohibits any person from possessing or having under his or her control any hypodermic needle or syringe, except in accordance with those regulatory provisions.

This bill would delete the prohibition against any person possessing or having under his or her control any hypodermic needle or syringe, except in accordance with the aforementioned regulatory provisions.

Existing law, until December 31, 2010, authorizes a county or city to authorize a licensed pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person 18 years of age or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with a local health department in the Disease Prevention Demonstration Project, established by law to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of bloodborne pathogens, including HIV and hepatitis C.

This bill would, instead, for the period beginning January 1, 2011, and ending December 31, 2018, permit a physician or pharmacist, without a prescription or a permit, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older and would permit a person 18 years of age or older, without a prescription or license, to obtain 30 or fewer hypodermic needles and syringes solely for personal use from a

physician or pharmacist. This bill would make conforming changes, including the elimination of the Disease Prevention Demonstration Project.

Under existing law, it is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking specified controlled substances.

Existing law, until December 31, 2010, provides that the above-described provisions, pursuant to authorization from a city or county, shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes.

This bill would, instead, provide that the above-described provisions making it unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia for unlawfully injecting or smoking certain controlled substances shall not apply for the period beginning January 1, 2011, and ending December 31, 2018, to possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

This bill would require the state Office of AIDS to develop and maintain information on its Internet Web site to educate consumers at risk of bloodborne infections of opportunities to improve and protect the consumer's health, and to protect the public health and would also require the California State Board of Pharmacy to post, or post a link to, this information on its Internet Web site.

The Pharmacy Law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes. Existing law makes it a crime to knowingly violate any provision relating to the Pharmacy Law.

This bill would amend the Pharmacy Law to require pharmacies that furnish nonprescription hypodermic needles and syringes to store the hypodermic needles and syringes in a manner that ensures that they are not accessible to unauthorized persons, and would require pharmacies to provide consumers with prescribed options for consumer disposal of hypodermic needles and syringes. This bill would also require the pharmacies to provide written information or verbal counseling at the time of furnishing or sale of nonprescription hypodermic needles or syringes, as specified.

By changing the definition of an existing crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to improve access to syringes and hypodermic needles so as to remove significant barriers for persons seeking to protect their health and the health of other persons, and to remove barriers for programs or businesses to provide sterile injection equipment and education to adults, thereby reducing the spread of communicable diseases and protecting the public health.

SEC. 2. Section 4140 of the Business and Professions Code is repealed.

SEC. 3. Section 4145 of the Business and Professions Code is amended to read:

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, for the period beginning January 1, 2011, and ending December 31, 2018, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of

age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(d) Pharmacies that furnish nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, pharmacies that furnish nonprescription hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program.

(2) It shall furnish, or make available, mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a personal medical sharps disposal container that meets applicable state and federal standards for disposal of medical sharps waste.

(f) Pharmacies that furnish nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

- (1) Access drug treatment.
- (2) Access testing and treatment for HIV and hepatitis C.
- (3) Safely dispose of sharps waste.

SEC. 4. Section 4148 of the Business and Professions Code is amended to read:

4148. All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person

holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144, or 4145, or under Section 11364, 121349, or 121349.1 of the Health and Safety Code.

SEC. 5. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) For the period beginning January 1, 2011, and ending December 31, 2018, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

SEC. 6. Section 121281 is added to the Health and Safety Code, to read:

121281. In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting the consumer's health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

SEC. 7. Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code is repealed.

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2010

Governor

Attachment A-4

Previously Approved Board-Sponsored Legislation

Section 4362 – Pharmacists Recovery Program

Sections 4040.5, 4081 and 4126.5

Reverse Distributors

Sections 4104, 4105, and 4112

Enforcement Enhancements

§ 4362. Entry into the Pharmacists Recovery Program

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

- (1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.
- (2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of \$125 monthly to cover a portion of the administrative costs borne by the board to contract for these services. This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

§ 4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned by the patient or the patient's agent to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient or a patient's agent to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler as defined in Health and Safety Code section (insert number here).

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

§ 4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
- (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
- (3) A licensed wholesaler acting as a reverse distributor.
- (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
- (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- (7) To another pharmacy under common control.

(8) A licensed integrated waste hauler, as defined in Health and Safety Code section (insert section number), for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy.

(9) Add language dealing with the return of drugs to pharmacy by consumers when Class I recall ordered by FDA. (Not sure what language we would need here; let's discuss further.)

§ 4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all drugs returned to a wholesaler or provided to a reverse distributor shall document the quantity or weight of the drugs returned, the date the drugs were returned and the names of the reverse distributors or wholesalers entity to whom the drugs were provided. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the date and name of the licensed integrated waste hauler. For the purpose of this section, "licensed integrated waste hauler" means a person or entity as defined in Health and Safety Code section (insert number here).

PROVISION 1:

Amend §4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures

Why Needed: when a pharmacy identifies a theft of drugs by an employee, the pharmacy would be required to provide the board with an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results. This would greatly aid the board in pursuing prosecution more quickly.

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

PROVISION 2:

Amend §4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(b) When requested by an inspector or authorized representative of the board, the owner, corporate officers, or manager of any entity licensed by the board shall provide the board with records as requested within 72 hours of the request. The entity may request an extension of this timeframe for a period up to 14 days. Such a request must be made in writing and is subject to approval.

~~(e)~~ (f) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

~~(f) This section shall become operative on January 1, 2006.~~

PROVISION 3:

Amend §4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Why Needed: To prevent an individual whose pharmacist license has been revoked in California from working in another state as a pharmacist to dispense medication mailed to patients in California. Mail order is one way many patients receive medication from their health plans. If California revokes a pharmacist from practicing in this state, it undermines the board's public protection efforts if the pharmacist can still dispense medication to California patients from outside the state.

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.

~~(d)~~ (e) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

~~(e)~~ (f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

~~(f)~~ (g) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~ (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~ (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~ (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

Attachment A-5

Legislation for Consideration For The 2011/2010 Session

Section 4200 – Pharmacist Examination

*Section 4301.1. Suspension of License for Felony Conviction
for a Crime of Unprofessional Conduct*

Proposal to Amend § 4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

§ 4200. (a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has ~~passed a written and practical examination given by the board prior to December 31, 2003, or has~~ passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Add § 4301.1. Pharmacist License; Suspension; Felony Conviction

(a) The board (may? shall?) suspend the license of a pharmacist convicted of a felony for a crime of unprofessional conduct as specified in section 4301. The board shall notify the pharmacist of the license suspension and of his or her right to have the issue of penalty heard as provided in this article.

(b) Upon its own motion or for good cause shown, the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the pharmacy profession.

(c) The issue of penalty shall be heard by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, as determined by the board.

(d) A pharmacist may request a hearing on the penalty and that hearing shall be held within 90 days from the date of the request. If the order suspending the pharmacist's license or authority to practice pharmacy is overturned on appeal, any discipline ordered pursuant to this section shall automatically cease.

(e) If an accusation for permanent discipline is not filed within 90 days of the suspension imposed pursuant to this section, the suspension shall automatically terminate.

(f) For a suspension issued pursuant to this section, the pharmacist may request that the hearing on the penalty conducted pursuant to this section be held at the same time as a hearing on the accusation.

Attachment B-1

Possible Rulemaking

Add §1707.6 – Notices to Consumers

***Amend §1707.2. Notice to Consumers and
Duty to Consult***

Potential Regulatory Proposal(s) re: Notices to Consumers

OPTION 1: DISCUSSED AT JULY 29, 2010 BOARD MEETING

Delete 16 CCR § 1707.2, subs. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, notices containing the text in subdivisions (b), (c), (d) and (e). The board has previously developed and distributed standardized posters for the notices that are required by subdivisions (b) and (c). The board shall similarly develop a standardized poster for the notice required by subdivision (d). For the notices required by subdivisions (b), (c), and (d), the pharmacy shall display the poster developed by the board, or a full-color duplicate thereof.

As an alternative to printed notices, the pharmacy may display one or more required notices on a video screen located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, where the video screen display meets the following requirements:

- (1) The video screen is at least 30 inches, measured diagonally;
- (2) The text and format of the notice(s) is the same as it would be in printed form, including the size of the notice(s), the size of the text, and the colors utilized;
- (3) The text of the notice(s) remains on the screen for a minimum of 30 seconds;
- (4) Where the entire text of a notice does not fit onto a single screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least 30 seconds; and
- (5) No more than four minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

Staff Note: Subdivision (b) is the Notice to Consumers currently at § 1707.2, subd. (f)

(b) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?

How and when do I take it - and for how long? What if I miss a dose?

What are the possible side effects and what should I do if they occur?

Will the new medicine work safely with other medicines and herbal supplements I am taking?

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

Staff Note: Subdivision (c) is the Notice to Consumers currently at § 1707.2, subd. (g)

(c) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy.
2. The pharmacist, based upon his or her professional judgment determines providing the item:
 - is against the law,
 - could cause harmful drug interaction, or
 - could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

(d) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

The container label for your prescription medication contains vital information. Please take a moment to check the container label before you leave the pharmacy to be sure that:

The container label has the correct patient name;

The container label has the correct medication name and strength;

The container label has the correct directions for use; and

The container label includes the purpose or condition for which the medication was prescribed, if that information was included in the prescription.

All of these four categories of information must be clustered into one area of the label, and must appear on the label, in the order given above, in at least a 10 point font.

If you would like the text on your container label to be larger, please ask. Upon request, the pharmacy will print a label with the text for these four categories of information in at least a 12-point font. This may result in use of a larger label and/or a larger container.

If you have questions about any of the information on the label, ask the pharmacist.

(e) There shall be a notice containing the following text, repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice:

NOTICE TO CONSUMERS

It is very important that you understand the information on the container label for your prescription medication. If you have trouble reading or understanding English, this pharmacy will make interpretive services available to you in your own language.

(f) The pharmacy shall also post or provide the following statement, repeated in English and in each of the languages for which interpretive services are available, written in at least an 18-point boldface type in a color that sharply contrasts with the background color of the statement, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This statement, repeated in all available languages, may be made available by posted notice or by video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance.

If the posted notice or video screen is not positioned so that a consumer can easily point to and touch the notice or video screen, the statement, repeated in all available languages, shall be made available on a cardstock flyer or handout kept within reach of consumers at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Such flyer/handout shall be at least 8 inches by 11 inches, on at least 8 point cardstock, which may be laminated. At least one copy of the flyer/handout shall be available at all hours that the pharmacy is open.

OPTION 2: NEW STAFF PROPOSAL BASED ON JULY 29, 2010 BOARD DISCUSSION

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to give such approval to a committee or the Executive Officer. The pharmacy may also or instead display the notice on video screen(s) located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, so long as: (1) the video screen is at least 30 inches, measured diagonally; (2) The text, format, size, and colors utilized are the same as the poster-sized notice; (3) The notice remains on-screen for a minimum of sixty (60) seconds; and (4) Where the text of the notice does not fit on one screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least sixty (60) seconds.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

You may ask this pharmacy to use larger print on your prescription drug labels.

Interpretive language services will be made available to you in this pharmacy at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost or a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not in stock, or cannot be immediately provided, the pharmacy will work with you to ensure that you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text repeated in English and in each of the languages for which interpretive services are available, printed in an least an 18-point boldface type in a color that sharply contrasts with the background color of the notice, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This text shall be repeated in at least fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medi-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California.

The pharmacy may post this notice in paper form or on a video screen meeting the requirements of subdivision (a) if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a cardstock flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer/handout shall be at least 8 1/2 inches by 11 inches, shall be printed on durable cardstock, and may be laminated.

Attachment B-3

Board Adopted Regulations

Sections 1721 and 1723.1

*Dishonest Conduct on a Pharmacist Licensure Examination;
Confidentiality*

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1721. Dishonest Conduct During Examination

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

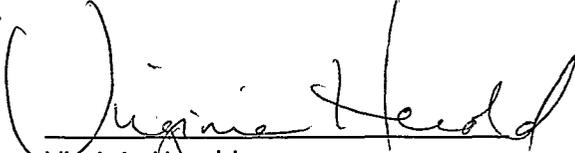
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123, 496, and 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.


Virginia Herold

Executive Officer
Board of Pharmacy

Attachment B-4

Board Adopted Regulations Undergoing Administrative Review

Adopted Text

*§1707.5. Requirements for Patient-Centered Prescription
Labels*

Order of Adoption
Board of Pharmacy
California Code of Regulations

Specific Language to Add Section 1707.5.

Add Section 1707.5. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels on Medication Containers.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use.

(D) Purpose or condition, if entered onto the prescription by the prescriber.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of

information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 [insert appropriate dosage form] at bedtime
- (B) Take 2 [insert appropriate dosage form] at bedtime
- (C) Take 3 [insert appropriate dosage form] at bedtime
- (D) Take 1 [insert appropriate dosage form] in the morning
- (E) Take 2 [insert appropriate dosage form] in the morning
- (F) Take 3 [insert appropriate dosage form] in the morning
- (G) Take 1 [insert appropriate dosage form] in the morning, and
Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and
Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and
Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert
appropriate dosage form] at noon, and 1 [insert appropriate dosage
form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert
appropriate dosage form] at noon, and 2 [insert appropriate dosage
form] in the evening

- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take [insert appropriate dosage form] at a time. Wait at least [] hours before taking again. Do not take more than [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

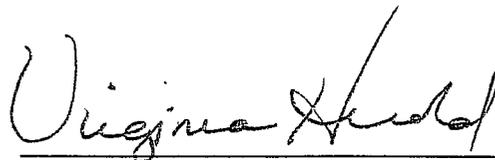
(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

Attachment B-5

Board Approved Regulations

Recently Noticed

(45-Day Comment Period is

October 8 – November 22, 2010)

§1732.2. Board Accredited Continuing Education

Title 16. Board of Pharmacy Proposed Language

To Amend Section 1732.2. of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit hours for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education hours for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded up to six hours of continuing education on an annual basis. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance

sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded up to two hours of continuing education on an annual basis. A maximum of four continuing education hours may be earned each year by attending the full meetings of two different board committees. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) A pharmacist who completes the Pharmacist Self-Assessment Mechanism (PSAM) administered through the National Association of Boards of Pharmacy, may be awarded up to six hours of continuing education.

(g) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4200.2, 4202, 4231 and 4232, Business and Professions Code.

Attachment C

First Quarterly Report on Legislation / Regulations Committee Goals For 2010/2011

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<p>1. Secure extension of board's sunset date.</p> <p><i>1st Qtr 06/07: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i></p> <p><i>4th Qtr 06/07: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i></p> <p><i>1st Qtr 08/09: SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i></p> <p><i>Governor signs SB 963 (Chapter 385, Statutes of 2008)</i></p> <p><i>1st Qtr 09/10: Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</i></p> <p><i>2nd Qtr 09/10: Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</i></p> <p><i>3rd Qtr 09/10: Sunset bills introduced</i></p> <p><i>AB 1659 (Huber) – State Government, Agency Repeals</i></p> <p><i>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</i></p> <p><i>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</i></p> <p><i>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</i></p> <p><i>4th Qtr 09/10: SB 954 (Harmon) – Bill is dead (Failed deadline)</i></p> <p><i>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</i></p>

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions

Oct. 2007: Board sponsors omnibus provisions for 2008. Four types of changes are discussed.

(1) Changes specific to the PIC and DRC requirements

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
- Section 4036.5 – Pharmacist-in-Charge
- Section 4161 – Nonresident wholesaler
- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
- Section 4329 – Nonpharmacists; Prohibited Acts
- Section 4330 – Proprietors; Prohibited Acts

(2) Changes to allow for the use of mobile pharmacies

- Section 4062 – Furnishing Dangerous Drugs During an Emergency.
- Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.

(3) General changes

- Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.
- Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.
- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) Changes based on recodification of Business and Professions Code section 4052

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

Jan. 2008:	<i>Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.</i>
	<i>Board approved language for omnibus bill.</i>
April 2008:	<i>Some provisions of omnibus bill removed:</i>
	<ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i>
Oct. 2008:	<i>Governor vetoes SB 1779</i>
1st Qtr 08/09:	<i>Board seeks to pursue omnibus provisions (formerly contained in SB 1779).</i>
	<i>Four areas of change:</i>
	<i>(1) Changes specific to the PIC and DRC requirements</i>
	<ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i>
	<i>(2) Changes to allow for the use of mobile pharmacies</i>
	<ul style="list-style-type: none"> • <i>Section 4062 – Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.</i>
	<i>(3) General changes</i>
	<ul style="list-style-type: none"> • <i>Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> <p><i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i></p>

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

1st Qtr 08/09: *Board seeks to introduce additional changes:*

- *Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

New Provisions

- *4200.1 – Pharmacist Examination; Remedial Education*
- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

2nd Qtr 08/09: *Provisions contained in SB 821:*

- *Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*

New Provisions

- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

3rd Qtr 08/09: Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.

Jan. 2010: Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.

Omnibus Proposal #1:

- (1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)
 - §4017 – Authorized Officers of the Law
 - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - §4028 – Definition of Licensed Hospital
 - §4037 – Definition of Pharmacy
 - §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
 - §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
 - §4101 – Pharmacist-in-Charge, Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board Prescription: Exceptions.
 - §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
 - §4127.1 – License to Compound Injectable Sterile Drug Products Required
 - §4169 – Prohibited Acts (also, strike operative date of 2008)
 - §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - §4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs
- (2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
 - §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- (3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)
 - §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative-in-Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.

*4th Qtr 09/10: Board establishes support position of SB 1489.
SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies.
SB 1489 is amended to modify §4076.5 – Patient-Centered Prescription Labels to authorize the board to exempt long-term health care facilities from regulations.*

1st Qtr 10/11: Governor signs SB 1489 (Chapter 653, Statutes of 2010).

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sep. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.

Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12)

Oct. 2009: Board approves regulatory language for Initial Notice.

Jan. 2010: Office of Administrative Law approves regulation.

July 2010: Regulation effective.

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sep. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.

Sep. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.
- Oct. 2007:** **Governor signs the following:**
AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.
SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.
- Governor vetoes the following:**
AB 249 (Eng) Healing Arts: Settlement Agreements.
AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.
AB 1025 (Bass) Professions and Vocations: Denial of Licensure.
SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.
- Oct. 2008:** **Governor signs the following:**
AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks
SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review
- Governor vetoes the following:**
AB 501 (Swanson) Pharmaceutical Devices
AB 865 (Davis) State Agencies
AB1574 (Plescia) Surgical Clinics: Licensure
- Jan. 2009:** *Legislation introduced affecting Pharmacy law:*
(New Session) *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.*
SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.

4th Qtr 08/09: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
 AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)
 AB 1370 (Solorio) “Best Before” Date on a Prescription Label
 AB 1458 (Davis) Drugs: Adverse Effects Reporting
 SB 26 (Simitian) Home-Generated Pharmaceutical Waste
 SB 43 (Alquist) Cultural and Linguistic Competency
 SB 238 (Calderon) Medical Information
 SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
 SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
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 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts

1st Qtr 09/10: Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts

2nd Qtr 09/10: Governor signs SB 819 (Omnibus)
 Governor vetoes SB 820 (Omnibus)
 Governor signs SB 821 (Omnibus)
 Governor signs SB 470 (Corbett) - “Purpose”
 Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset
 Governor signs AB 931 (Fletcher) - Emergency Supplies Container
 Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia

3rd Qtr 09/10: Board considers new legislation

1. *Board of Pharmacy*
 - *AB 2104 (Hayashi) – California State Board of Pharmacy*
 - *SB 1390 (Corbett) – Prescription Container Labels*
2. *Pharmacy Practice*
 - *AB 1869 (Anderson) – Pharmacy (spot bill)*
 - *AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors*
3. *Sunset Review and Legislative Oversight Proposals*
 - *AB 1659 (Huber) – State Government, Agency Repeals*
 - *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection*
 - *SB 954 (Harmon) – Legislative Procedure, Committee Referrals*
 - *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations*
 - *SB 1172 (Negrete McLeod) – Sunset of Diversion Program*
4. *Regulation of Dangerous Drugs and Devices*
 - *AB 1455 (Hill) -- Pseudoephedrine*
 - *AB 2548 (Block) – CURES – Prescription Drug Monitoring Program*
 - *SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products*
 - *SB 1071 (DeSaulnier) – CURES*
 - *SB 1106 (Yee) – Prescribers – Dispensing of Samples*
5. *Pharmacy Licensing Issues*
 - *AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies*
 - *AB 2292 (Lowenthal) – Pharmacy: Clinics*
 - *AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program*
6. *Distribution of Needles and Syringes*
 - *AB 1701 (Chesbro) – Hypodermic Needles and Syringes*
 - *AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services*
 - *AB 2139 (Chesbro) – Solid Waste: Product Stewardship*
 - *SB 1029 (Yee) -- Hypodermic Needles and Syringes*
7. *General / Other*
 - *AB 2112 (Monning) – Prescription Record Privacy Act*

	<p>4th Qtr 09/10: Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p>Apr. 2010: Board takes positions on legislative measures: AB 1701 (Chesbro) Support AB 2104 (Hayashi) Oppose AB 2292 (Lowenthal) Support SB 1106 (Yee) Support if Amended AB 1916 (Davis) Bill is dead (failed deadline) AB 2112 (Monning) Bill is dead (failed deadline) SB 1111 (Negrete McLeod) Bill is dead (failed deadline)</p> <p>May 2010: AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p>June 2010: SB 1390 (Corbett) Fails passage in policy committee SB 954 (Harman) Bill is dead (failed deadline) SB 1171 (Negrete McLeod) Bill is dead (failed deadline) AB 2139 (Chesbro) Bill is dead (failed deadline) AB 2292 (Lowenthal) Bill is dead (failed deadline) AB 2548 (Block) Bill is dead (Failed deadline)</p> <p>Apr./May 2010: AB 2104 (Hayashi) Amended twice</p> <p>June 2010: AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p> <p>July 2010: AB 2077 (Solorio – Centralized Hospital Packaging Pharmacies. Board establishes Support position.</p>
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1st Qtr 10/11: Governor signs the following legislation:

AB 2104 (Hayashi) – Requires DCA Director approval of the Board's appointment of Executive Officer (Chapter 374, Statutes of 2010)

AB 1659 (Huber) – State Government, Agency Repeals (Chapter 666, Statutes of 2010)

AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection (Chapter 670, Statutes of 2010)

SB 1172 (Negrete McLeod) – Diversion Programs (Chapter 517, Statutes of 2010)

AB 1071 (Chesbro) – Hypodermic Needles and Syringes (Chapter 667, Statutes of 2010)

SB 1414 (Hill) – Apomorphine: Unscheduled (Chapter 76, Statutes of 2010)

AB 2699 (Bass) – Licensure Exemption: State of Emergency (Chapter 270, Statutes of 2010)

Governor vetoes the following legislation:

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes

SB 1029 (Yee) – Hypodermic Needles and Syringes

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

AB 2747 (Lowenthal) – Prisons: Pharmacy Services

The following legislation fails passage:

AB 1455 (Hill) – Pseudoephedrine

SB 1071 (DeSaulnier) – CURES

SB 1106 (Yee) – Prescribers Dispensing of Samples

AB 2551 (Hernandez) – Pharmacy Technician Scholarship & Loan Repayment Program

AB 1310 (Hernandez) – Healing Arts Database

7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.
- March 2007: Licensing Committee considers and approves concept. More work is required.*
- June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.*
- Sept. 2007: Licensing Committee forwards to full board legislative proposal.*
- Oct. 2007: Board approved draft legislation.*
- Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.*
- Dec. 2007: Staff develop fact sheets and work with experts in immunizations.*
- Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.*
- April 2009: Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.*
- May 2009: Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)*
- Jan. 2010: Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.*
- Jan. 2010: AB 977 passes out of Assembly Health Committee
Board reaffirms "support" position.*
- April 2010: Board changes position from "sponsor" to "support".*
- June 2010: AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy. Bill died in committee.*

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.

Apr. 2008: First public forum held in Fremont.

*May 2008: Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.*

June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.

July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.

Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.

Public Education Committee updated on the status of survey results.

Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.

May 2009: Bill passes out of the Senate

Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).

Oct. 2009: Board approves regulatory language for notice.

Nov. 2009: Regulatory effort initiated

June 2010: Board adopts final text (See Objective 3.2, Task 16)

Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.

9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.

Dec. 2008: Board receives findings of independent fee audit.

Jan. 2009: Board votes to pursue fee increase.

Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.

June 2009: Bill passes out of the Assembly.

Sept. 2009: Bill is enrolled and sent to the Governor.

Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.

Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)

Jan. 2010: Statutory fee schedule implemented (supersedes 16 CCR 1749)

10. Advocate legislation to enhance the board's enforcement activities.

Jan. 2010: Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.

Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.

Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> 3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Oct. 2007: Board approves regulation for 45-day comment period.</i> <i>May 2009: Regulation and revised Disciplinary Guidelines approved and takes effect.</i> 6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 7. Exempt the address of records of interns from display on the board's Website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i> 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). <i>Feb. 2007: Board notices regulation for 45 days comment period.</i> <i>Nov. 2007: Regulation changes takes effect.</i> <i>Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.</i>

- 10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.**
- Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:*
- 1707 – Waiver of requirements for off-site storage of records*
 - 1709.1 – Designation of pharmacist-in-charge*
 - 1715 – Self-assessment of a pharmacy by the pharmacist-in-charge*
 - 1717 – Pharmacy practice*
 - 1746 – Emergency contraception*
 - 1780.1 – Minimum standards for veterinary food-animal drug retailers*
 - 1781 – Exemption certificate*
 - 1787 – Authorization to distribute dialysis drugs and devices*
 - 1790 – Assembling and packaging*
 - 1793.8 – Technician check technician*
 - Repeal section 1786 – Exemptions*
- March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*
- 11. Increase fees to keep the board's contingency fund solvent and maintain operations.**
- Nov. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.*
- Jan. 1, 2008: New fees take effect.*
- Oct. 2009: Governor signs AB 1071, new fee schedule.*
- Jan. 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)*
- 12. Secure regulatory standards for pharmacies that compound. (§1735 et al)**
- Nov. 2007: Board releases language for the 45-day comment period.*
- Sep. 2008: Board releases (withdrawn) language for 45-day comment period.*
- Oct. 2008: Regulation hearing*
- Jan. 2010: Office of Administrative Law approves regulation.*
- July 2010: Regulation and Self-Assessment Form 17M-39 is effective. Board staff developing fact sheet for pharmacies.*
- 13. Establish an ethics course (§1773 and §1773.5).**
- Sep. 2008: Board notices regulation for 45-day comment period.*
- Sep. 2009: Regulation takes effect.*
- 14. Pharmacist Renewal Requirements (§1702).**
- Dec. 2009: Board notices regulation for 45-day comment period.*
- Feb. 2010: Board adopts regulation.*
- June 2010: Office of Administrative Law approves regulation (to be effective Dec. 2010)*
- 15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).**
- Oct. 2009: Board notices regulation for 45-day comment period.*
- Jan. 2010: Board adoption of regulation as noticed.*
- July 2010: Rulemaking submitted to the Office of Administrative Law for review.*
- Aug. 2010: Office of Administrative Law approves regulation.*
- Sep. 2010: Regulation takes effect.*

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| | <p>16. Standardized, Patient-Centered Prescription Labels
 <i>Oct. 2009: Board approves language to initiate rulemaking.</i>
 <i>Nov. 2009: Board notices regulation for 45-day comment period.</i>
 <i>Jan. 2010: Regulation hearing.</i>
 <i>Feb. 2010: Board modifies text of regulation.</i>
 <i>Board notices modified text for 1st 15-day comment period.</i>
 <i>Apr. 2010: Board modifies text of regulation.</i>
 <i>Board notices modified text for 2nd 15-day comment period.</i>
 <i>June 2010: Board adopts regulation language noticed on April 28.</i>
 <i>July 2010: Rulemaking submitted to Department for review.</i>
 <i>Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.</i></p> <p>17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746)
 <i>Jan. 2010: Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.</i></p> <p>18. Board Issued Continuing Education (CE) Credit (§1732.2)
 <i>Feb. 2010: Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.</i>
 <i>Oct. 2010: Board notices regulation for 45-day comment period.</i></p> <p>19. Notice to Consumers re: Patient-Centered Prescription Labels
 <i>Apr. 2010: Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.</i></p> <p>20. Update references to USP Standards (§1780)
 <i>1st Qtr 07/08: Board considers review of USP references.</i>
 <i>2nd Qtr 07/08: Subcommittee established to conduct full review of USP updates needed.</i></p> <p>21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785)
 <i>1st Qtr 07/08: Board approves regulation for notice.</i>
 <i>2nd Qtr 07/08: Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.</i></p> <p>22. Accreditation Agencies for Pharmacies that Compound (§1751.x)
 <i>1st Qtr 07/08: Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)</i></p> |
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Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</p> <p><i>Sept. 2009:</i> SB 819 and SB 821 enrolled and sent to the Governor.</p> <p><i>Oct. 2009:</i> Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</p>